Exhibit 5

Daniel Fabricant, Ph.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA, Plaintiff, vs. UNDETERMINED QUANTITIES OF 1,3-DIMETHYLAMYLAMINE HCl (DMAA), Defendant, and HI-TECH PHARMACEUTICALS, INC., and JARED WHEAT, Claimants.	Civil Action No. 1:13-cv-13675-WBH-JCF

Deposition of Daniel Fabricant, Ph.D.
Washington, D.C.
Monday, November 21, 2016
9:30 a.m.

Job No. 115859
Reported by: Laurie Donovan, RPR, CRR

Daniel Fabricant, Ph.D.
Deposition of
DANIEL FABRICANT, Ph.D.

Held at the offices of:
United States Department of Justice
Consumer Protection Branch
450 5th Street, N.W.
Washington, D.C. 20001

Taken pursuant to notice, before Laurie Donovan, Registered Professional Reporter, Certified Realtime Reporter, and Notary public in and for the District of Columbia.

Daniel Fabricant, Ph.D.
APPEARANCES

ON BEHALF OF THE PLAINTIFF:
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By: Joshua Davenport, Esq.

- and -

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By: Jack Wenik, Esq.

Daniel Fabricant, Ph.D.
EXAMINATION INDEX

E X H I B I T S

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(Exhibits continued)

P R O C E E D I N G S

DANIEL FABRICANT, Ph.D.,
having been first duly sworn, testified upon his oath as follows:

EXAMINATION BY COUNSEL FOR DEFENDANT

BY MR. WENIK:

Q Good morning, Dr. Fabricant, and thank you for coming.

Have you been deposed before?

A Yes.

Q So I assume you're somewhat familiar with the procedure, but for the benefit of the record, I'll put a couple of things before you.

One is that your testimony is being taken under oath, so we need an oral response for the stenographer, not a nod of the head or a gesture.

The other thing is if I ask you a question and you didn't hear it, didn't understand it, you know, please speak up, ask me to rephrase or repeat it. Otherwise, I'll assume you've understood the question and heard it.

And if I use a term, particularly a medical or scientific term, improperly or

mispronounce it, feel free to correct me.

Other than that, do you have any questions for me before we begin?

A No.

(Exhibit 1 was marked for identification.)

BY MR. SCOTT:

Q So, Doctor, I've placed before you what I've marked as Fabricant Exhibit 1, the subpoena for testimony in this case, and you are appearing pursuant to the subpoena in this matter?

A Yes.

Q All right. Is the government representing you for purposes of these proceedings?

A Yes.

Q Do you have your own counsel involved in this, or just you're relying on the government?

A Right now just relying on the government.

Q Okay. That may be a mistake, but that's okay.

So the government lawyers can interpose objections when they want to, when they feel

something is inappropriate, but other than an instruction not to answer a question because of some privilege, you should put an answer on the record. Okay?

So just a couple of housekeeping things. Could you state and spell your full name for the record?

A Daniel Stuart Fabricant, D-A-N-I-E-L, S-T-U-A-R-T, F-A-B-R-I-C-A-N-T.

Q And what is your business address, Doctor?

A 440 First Street, Washington, D.C.

Q And your home address?

A 4307 Chesapeake Street, D.C.

Q For purposes of today's deposition, what did you do to prepare, other than any confidential attorney/client privileged conversation? Did you review any documents? Did you have any discussions with anyone?

A Just discussion with the government attorneys.

Q Okay.

Let me ask you a little bit about your background, because I don't have the benefit of

your CV.

First of all, have you ever testified -- let me rephrase that.

Have you ever been retained as an expert witness in a litigation?

A Yes.

Q All right. In what sort of subject matters have you been retained as an expert?

A Regulatory status, chemistry, toxicology, foods and dietary supplements.

Q And have those matters been where you've been retained by the government or private industry?

A Private industry.

Q Okay, and how often have you been retained as an expert?

A Three cases.

Q And do you remember the names of those cases?

A Yes. Two are under seal, but it's -- they're both against Monster Energy, and one was a company called Happy versus Procter & Gamble.

Q And what sort of matters were these? Were these patent cases, intellectual property

cases?

A No. Regulatory, dealing with regulatory status of ingredients, safety/toxicology of ingredients, FDA Food, Drug and Cosmetic Act law.

Q All right. Have you ever testified in a court of law as an expert as opposed to a deposition?

A Only my divorce hearing.

Q I don't need to go into that.

I take it in those three matters you prepared expert reports of some sort?

A I did.

Q Okay. Other than the divorce matter which I'm not interested in, have you ever testified in a public trial or arbitration or hearing of any sort?

A No.

Q Have you ever --

A Well, actually, two Senate hearings would count, I guess, under that, in front of Senate Judiciary in 2009, in front of Senate Commerce in 2014.

Q Okay. What was the subject matter of what you testified?

A Senate Judiciary was on dietary supplements, anabolic steroids, and 2014 was on claims, dietary supplement claims, and the Federal Trade Commission.

Q And in those two matters -- well, let's take the 2009 first. I'm not going to do a compound question.

So were you testifying as a representative of the Natural Products Association in 2009?

A Yes, I was.

Q And in the 2014 matter, was that --

A Same. Natural Products Association.

Q Okay.

Have you ever been convicted of a crime?

A Traffic offenses.

Q I'm not interested in those.

Have you ever been a party to a litigation as a plaintiff or defendant? And let me add I'm not interested in your divorce or an auto accident. I mean in your professional capacity.

A Yes.

Q And tell me about those.

A Well, when I was at FDA, there were obviously a number of cases that were brought against the government, some for regulatory and final agency action, and then there's been some suits at NPA, mostly labor type stuff.

Q EEOC type complaints, discrimination type things?

A Yes, mostly EEOC or wrongful termination, those kinds of things.

Q All right. Let me ask you a little bit about your education.

My understanding is that you have a degree in chemistry from the University of North Carolina; is that right?

A My undergraduate degree, yes.

Q When did you get that?

A 1997.

Q And was there a particular area of chemistry that you majored in? Was it organic or some other type or just chemistry in general?

A I had a specialty in organic. I took extra course work in organic.

Q And I also understand that you have a Ph.D. in pharmacognosy; is that right?

A That's correct.
Q And is that from the University of Illinois Chicago?
A Yes.
Q When did you get that?
A 2005.
Q Any other graduate degrees or other higher education?
A The government sent us to Harvard Kennedy School for the Strategic Management of Regulatory and Enforcement Agencies. We did that in 2012.
Q I suppose I should ask, even though I know what it means, but to flesh out the record, what is pharmacognosy?
A It's the study of natural products. It's development of medicines from generally plants.
Q And were you involved in, when you were having your course work in the Ph.D., in research into botanicals?
A Yes.
Q And was that as part of the Botanical Research Center at the University of Illinois?

A Yes.
Q And did you work with Dr. Van Breeman?
A He wasn't my advisor, but he was on my defense committee, my dissertation defense committee.
Q Okay. What is your view of the academic reputation of Dr. Van Breeman?
A Very good.
Q Have any questions about his integrity?
A No reason to.
Q His scientific knowledge?
A No reason to.
Q And what was the subject of your dissertation?
A Black cohosh. It's a plant that grows in the Appalachians. It's used for menopause.
Q Have you published any articles or research in peer-reviewed literature?
A Yes.
Q Approximately how many articles have you published?
A About 20.
Q And what are the, generally, the subject areas of interest to you in your research that

you've published?
A Everything from botanical dietary supplements to drug discovery to regulatory status to toxicology, so a pretty wide range.
Q Okay. Have you published anything regarding DMAA?
A Yes.
Q What sorts of articles have you published?
A There's a book chapter in "Regulatory Toxicology" which touches on DMAA.
Q I'm sorry. The name of that book -- is that a textbook or --
A Yes, it's a textbook.
Q And what's the title of that textbook?
A "Regulatory Toxicology."
Q All right.
Do you hold any patents?
A No. Well, the Association does under my signature, but me personally, no.
Q Okay. What sorts of patents does the NPA hold that you were involved with?
A Trademarks. If you look on lip balms, we came up with a term to qualify what "natural"

is in the marketplace, so if you look at "natural personal care," we patented that, that mark.
Q Okay, and this book chapter that you were involved with in the "Regulatory Toxicology," do you remember roughly what year that may have come out or was public?
A It came out in 2015.
Q Okay.
So have you actually conducted research? And when I say "research," I don't mean reading like scientific literature, but I mean experimentation regarding DMAA either in animals, in humans, in vitro, in vivo.
Any original research that you personally conducted regarding DMAA?
A Do you mean that -- just so I'm clear, do you mean did I inject animals with DMAA?
Q Right. In other words, you know, I understand you must have done some research to publish this chapter in the sense of research and reading things, but I'm saying conducting an experiment of some sort, either in animals, in humans or what-have-you.
A No.

Q Let me ask you a little bit about some of your prior positions. I understand that you worked for Consumer Labs at one point?
A Yes.
Q What was your position with Consumer Labs?
A I was the assistant director for research.
Q And when was that?
A 2005.
Q And what were your duties as assistant director for research?
A Coordinated testing, both in the US and Japan, of a variety of consumer health products, primarily dietary supplements, and interpreted the research results for publication. That's kind of -- that was the base of it. Obviously there were a lot of other things involved, but that was largely the base of it.
And I also was the spokesperson sometimes for the organization, and I evaluated lab capabilities in terms of which labs were doing things the right way and which labs weren't.
Q So did Consumer Labs actually bring

products to market?
A No.
Q Would it do it on behalf of other companies?
A Consumer Lab was a -- they did independent testing of products that were already available for purchase at the consumer level.
Q I see, and how long did you hold this position with Consumer Labs?
A For 11 months.
Q And I understand that you've had a couple of different stints with the Natural Products Association; is that right?
A Two.
Q Tell me about the first one. What was your positions and when was it and what did you do?
A First I was hired in January of 2006 to be the vice president of science and regulatory affairs.
Q So would that have been right after you completed your Ph.D. that you began that position?
A Well, when I was at Consumer Lab, I had finished my Ph.D. I just needed to defend it,

so . . .
Q So it would be your Ph.D., Consumer Labs, then NPA; is that right?
A Yes.
Q Okay. So that first position, you were vice president of scientific affairs? Is that what you said?
A Scientific and regulatory.
Q And how long did you do that for?
A These years, three and a half years until I became interim CEO.
Q Okay, and what were your duties as the vice president of scientific affairs?
A Well, I was the organization's lead on all things scientific on interaction with scientific bodies, federal agencies, both domestic and abroad. Corralled the association members on different scientific positions. I wrote all the association's positions and comments on regulatory and scientific matters, as well as a spokesperson for the organization.
Q All right, and what did you do as the interim CEO?
A Ran the company, made sure that, you

know, we had, we had everything in the right place. Assumed the role of the chief of all advocacy functions, both domestic and abroad. We had a number of contracts as well, both with NIH and with Department of Commerce.
So it was pretty extensive, my role as CEO in that short period of time, but we got a lot done, it's about a three and a half million dollars organization. At that time we had 16 full-time staff, so obviously in charge of financially making sure that we were doing the right things.
Q What individuals or entities forms the bulk of the membership of the NPA, what sorts of entities or members of the Natural Products Association?
A It's split between manufacturers and retailers of natural health foods, natural products.
Q All right. Let's put the FDA aside for a moment.
A Okay.
Q So you're currently the CEO of the Natural Products Association; is that right?

A I am.
Q And are the duties that you have now similar to what you described or the same as when you were the interim CEO?
A No. There's a lot more going on, so they're enhanced.
Q All right. How are they enhanced?
A It's just very active. I think we're much more active congressionally, much more active in that regard.
Q All right. So were there any other positions that we've not discussed that you've held? We talked about Consumer Labs, we talked about NPA, and we're going to talk about the FDA in a little bit. Anything other than that that you've done occupation-wise?
A Well, I was employed by the University of Illinois when I was a graduate student. I was a research assistant. I had fellowships from NIH there, so -- and then I also worked for Viragen Pharmaceuticals. They were based in south Florida. They no longer function. I was an R&D chemist there and made interferon from human white blood cells instead of recombinant.

Q I see, and when did you do that?
A In 1997.
MR. WENIK: All right. So let me discuss for a moment before I begin talking about the FDA -- so gentlemen, I'm going to be showing Dr. Fabricant certain documents that are subject to the protective order, so rather than stop at each point in the deposition, what I propose is we just go through it, and after it's transcribed, you can designate whatever portions of the transcript you'd like as confidential or subject to the protective order rather than interrupt and put that on the record for each document.
MR. SCOTT: Are these documents that the government designated as confidential?
MR. WENIK: Correct.
MR. SCOTT: Well, that process is fine for those. Are there any that third parties have designated?
MR. WENIK: Not that I know of. What I'll be showing him that's designated as

confidential was by the government.
MR. SCOTT: Okay, and that's fine. I think there's a provision in the protective order that gives us some period of time to do that. We'll just deal with it then.
MR. WENIK: That's what I would suggest. Rather than interrupt the deposition as it's going on, after you get the transcript, you can go through the errata, submit whatever designations you'd like.
BY MR. WENIK:
Q So let me again get to why you're here is your position with the FDA. My understanding is that you were at the FDA from February of 2011 to April of 2014.
Does that sound about right?
A Yes.
Q And did you hold different positions during that time span, or did you hold the same position?
A The same.
Q And what was that position?
A Director of the Division of Dietary

Supplement Programs.
Q Okay, and what were your duties in that position?
A I was the agency's lead in all things dietary supplements. Reported to upper management on regulatory, legal, budgetary aspects. Really made sure the program was vital in terms of, as it's one of the core functions of FDA, at least on the food center, one of the -- you know, involved in food safety, also food additive safety, et cetera. Dietary supplements were under the Office of Nutrition, Labeling, and Dietary Supplements.
Q And approximately how many people did you supervise in your division?
A I had 26 FTEs.
Q Let me show you a document that has been previously marked as Keefe Exhibit 4. We'll mark it as Fabricant Exhibit 2.
(Exhibit 2 was marked for identification.)
BY MR. WENIK:
Q Dr. Fabricant, I've placed before you a document that I've marked for identification as Fabricant Exhibit 2, which, for the record, is an

organizational chart of the FDA in 2013.
Have you seen this before, by the way?
A Mm-hmm, yes.
Q Okay. So does this accurately reflect the organization of the FDA in 2013, as far as you can tell?
A Yes.
Q All right. I'm looking down at the bottom right corner where it says "Office of Nutrition, Labeling, and Dietary Supplements."
Is that the branch or subdivision, if you will, of the FDA that you were a part of?
A The office.
Q Okay, and Philip Spiller, who is listed here, what was his role?
A Well, he was the acting director after Barbara Schneeman retired.
Q Did you report to Mr. Spiller?
A I did.
Q And who would he report to?
A The center director, specifically -- well, they switched between the deputy directors, but largely the center directors. Sometimes we would report to Roberta Wagner, and sometimes we

would report to Steve Musser.
Q And where would you be in the chain of command here? Were you like the number two person under Mr. Spiller in the Office of Nutrition, Labeling, and Dietary Supplements, or how would you characterize it?
A Each office has divisions under this office, so I was one of the division directors under the office.
Q I see. So you would be the division director of dietary supplements?
A Correct.
Q Corey Hilmas; is that somebody that's familiar to you?
A Yes.
Q And was he with the FDA during your tenure there?
A Yes.
Q What was his position?
A He was originally a tox reviewer for the New Dietary Ingredient Notification Team, and then he was the head of the regulations and implementation branch.
Q And did he report to you?

A He did. He also served as an expert for the FDA.
Q And Mr. Hilmas, did he join you at the NPA after you left the FDA?
A Dr. Hilmas.
Q Dr. Hilmas, yes.
A Yes.
Q Did you know him before your stint with the FDA?
A No.
Q Jennifer Thomas; is that a name that's familiar to you from the FDA?
A Yes.
Q Who is she?
A She worked in the Office of Compliance at my time at the FDA.
Q All right, and that would be two boxes over here on the left?
A Yes.
Q All right, and what was her role at the FDA?
A She was the director of the Division of Enforcement at the Office of Compliance.
Q Now, when you were in the director

position of dietary supplements at the FDA, was one of your duties to take action against dietary supplements that you felt posed a hazard?
A Yes. Well, to clarify, it's not that we felt had a hazard; it was that we had evidence of a violation of the Food, Drug and Cosmetic Act.
Q And would you prioritize those substances that you thought or that the FDA believed posed a health hazard as opposed to some other violation?
MR. SCOTT: Object as to form.
THE WITNESS: We don't prioritize based on feeling; we base it on the evidence that we have.
BY MR. WENIK:
Q So if you had evidence that something posed a health hazard, would that be a priority as opposed to some other violation of an FDA regulation?
A With the Food, Drug & Cosmetic Act, any violation intimates a health hazard. It's mens rea, so you don't -- it doesn't necessarily -- if it's misbranded or adulterated, it's already, by law, deemed a health hazard.

Q Well, I guess let me put it this way: How would you prioritize when you were at FDA? Obviously, I can't expect you to testify to what's happening today, but when you were at FDA in that 2011 to 2014 block, how would you prioritize what violations to take action against? I assume there are more violations that occurred than you had resources to address; is that fair?

MR. SCOTT: Objection as to form. Objection; compound. That's two questions.

BY MR. WENIK:

Q Let me rephrase. That's a fair objection.

Would it be fair to say that during your tenure, your office became more violations of the Food, Drug & Cosmetic Act than you had resources to address?

MR. SCOTT: Object as to form.

THE WITNESS: We addressed anything that came up to us that we were knowledgeable about. That was the role of my office. We were the expert office, so when a case came in, either from the districts or something that we developed ourselves, we were

obligated to act, so I think -- you know, I don't -- I'm not sure of your question, I guess. I don't understand what it is you're trying to get to.

BY MR. WENIK:

Q Well, would you devote more resources to certain violations than others?

A It's on a case by case. You know, we took it case by case. It really depends on -- there's a process and the preponderance of the evidence, and we try to take it -- again, I think in dispatching our duties we did that. We really looked at a case-by-case scenario. Where a case required more resources, it was generally given more resources. Where a case may not have required more resources, it wasn't, but again it's always case by case.

Q And would you devote more resources to a case that your branch, if you will, your division felt posed a greater health risk to the public than others that posed less of a health risk?

MR. SCOTT: Object as to form.

THE WITNESS: Again, you're asking me to speculate. I'm not having -- we took

it case by case. I stand on my track record that we acted appropriately in all of our actions.

BY MR. WENIK:

Q All right.

Are you familiar with an individual at the FDA during your time period named Robert Moore?

A Dr. Moore, yes.

Q What is your recollection of what Dr. Moore's position was at the FDA?

A Dr. Moore was the lead for the regulations implementation team at the time, and he was there for eight months with me, and then he retired.

Q And he reported to you?

A Yes.

Q Was he someone that performed satisfactorily, in your view?

A Yes.

Q And what were his duties?

A He managed largely the interactions with the Office of Compliance, with the attorneys, and with a lot of stakeholders when I arrived. His

duties, because he was retiring, diminished, and he largely was focused on helping Dr. Hilmas manage that position in that branch, and Dr. Hilmas really applied his vision to what that branch should be.

Q What was his area of expertise?

A He had a degree in biochemistry.

Q Was he someone whose judgment you trusted?

A Bob, most of the time, yeah, he did a very good job most of the time. There was always -- I mean you always have a review of things, and one of the challenges when I arrived at the organization, and of no fault of Bob's, but there wasn't a lot of -- there wasn't a robust enforcement program or regulatory program in terms of dietary supplements when I arrived, and so that was largely what I was hired for was to try to, you know, get all of the functions operating.

Q To increase the robustness of it, for lack of a better word?

A To set up systems that increased the robustness of it, yes, to make it to where all parts of the law were being, you know, adequately

taken care of.
Q All right. Did you respect Dr. Moore's scientific judgment?
MR. SCOTT: Object as to form.
THE WITNESS: Is there a specific matter?
BY MR. WENIK:
Q Well, just generally, is he someone that you felt was competent and knowledgeable?
A In general, yes, and again, through no fault of his own, there was a culture of somewhat inactivity before my arrival, so we, you know, that was -- and he was retiring as well, so sometimes I think that he may have factored into some decision-making.
Q All right. Did you seek him out for advice regarding DMAA?
MR. SCOTT: Object as to form.
THE WITNESS: I sought out a lot of people for advice on DMAA. I sought out the whole division for advice on really the NDI provision and setting up a system to be more effective to the letter of the law.

BY MR. WENIK:
Q And was he one of the people that you may have reached out to?
A The whole division. I reached out to the whole division.
Q Okay. Let me talk a little bit more about your expertise.
Have you ever designed a human clinical trial?
A Yes.
Q How often have you done that?
A Probably, over the past two some years, probably about five or six trials.
Q And that's with the NPA?
A At NPA we have some members who have contract research organizations, and so we -- at times we'll advise them through either formal committees or through meetings.
Q Prior to the past two years you described, have you ever done that before, designed a human clinical trial?
A No. Animal studies.
Q Have you ever served as an investigator in a human clinical trial?

A I've been in a bioequivalence trial back when I was a graduate student.
Q And you mentioned that you've done some animal study work?
A Yes.
Q When did you do that?
A Both at NPA prior, and then my time at FDA, there were a few animal studies while I was at FDA and NPA that were published.
Q Have you ever served as a peer reviewer for a journal?
A Yes.
Q What journal have you served as a peer reviewer for?
A A number of them. I can't recall all of them offhand. I can provide my CV. They have them all listed there, but it's somewhere in the neighborhood of eight to ten journals. I can't recall the exact number at this time, but a number.
Q How long have you been doing that, serving as a peer reviewer?
A Since graduate school, so ten plus years.

Q What subject areas are these journals? Are these natural products journals or chemistry journals?
A Chemistry, natural products, regulatory, legal, a variety, a wide variety.
Q And as a peer reviewer, have you received manuscripts of research for your review?
A Yes.
Q Have you commented on that?
A Yes.
Q So let's talk a little bit then about the scientific method. What is your understanding of a case report, what a case report is?
MR. SCOTT: Object as to form.
THE WITNESS: Do you mean a case report in the literature that talks about some sort of health condition for one specific patient?
BY MR. WENIK:
Q Correct.
A Yes, I'm familiar with those.
Q All right, and is it as you described, it reports a medical event of some sort for an individual or individuals?

A Usually, yes.
Q In your mind, is a case report sufficient evidence to establish causation between a substance and a medical condition?
A They can be, depending on the quality of the case report.
Q Just the case report alone?
A If it's a good enough case report and there is underlying evidence, it could.
Q And what sort of underlying evidence would you look for?
A Medical history, challenge, dechallenge. Dechallenge is when you give an agent and then you take it away, and the symptoms recur. Those are generally some large confounders, but it would have to be on a case-by-case basis to establish what would make that case report stronger versus others, but those are some of the things you look for typically is -- the medical history is incredibly important.
Q Are you familiar with the Bradford Hill criteria for causation?
A Somewhat, but I'm not -- I need a refresher.

Q That Bradford Hill criteria, is that something you used or applied when you were at the FDA?
A No. Our officers used something called CIOMS by the World Health Organization.
Q And what's your understanding of what CIOMS is?
A CIOMS is at least globally recognized as the best way to evaluate an adverse event report or adverse event reports, and it gives a way to score and rank those adverse event reports and assign if it's possible, probable, there's a temporal relationship, if it's incomplete, if more information is need, if it's unlikely, and there's a lot that goes into evaluating those.
Q Would you prepare those, or other people at FDA would prepare those for you, those analyses?
MR. SCOTT: Object as to form.
BY MR. WENIK:
Q Let me repeat the question.
Those CIOMS analyses that you described, did you personally prepare those, or did others at FDA prepare those for you?

MR. SCOTT: Object as to form.
THE WITNESS: The medical officers prepared those.
BY MR. WENIK:
Q Let's return to peer reviewing for a moment. What is your understanding of what the function of peer review is?
A To make sure that there is appropriate scientific rigor.
Q Now, when something is published in a scientific journal, in your view, is it important that the information that's published be accurate?
A Yes.
Q Would that be something you'd be looking for as a peer reviewer?
A Yes.
Q Do most scientific studies begin with the researcher having a hypothesis of some sort?
A A hypothesis-driven research, yes.
Q And is the goal of scientific research, when one has a hypothesis, to either prove or disprove the hypothesis?
A Not necessarily.
Q And what else would be the goal?

A Well, sometimes you publish research that you have different findings. Serendipity comes into play as well, so it's not always that -- you know, you may venture down an avenue with a certain hypothesis and find out other things.
Q As a peer reviewer and as a scientist -- let me back up.
Do you consider yourself a scientist?
A Yes.
Q As a peer reviewer and as a scientist, do you believe it's appropriate for researchers to determine the conclusion of their research before they conduct the research itself?
A No.
Q Not appropriate?
A Well, that's why you have a hypothesis. You test it.
Q Is one of the things that you're looking for as a peer reviewer to see whether the researchers are biased?
MR. SCOTT: Object as to form.
THE WITNESS: Even if there is bias, that's the role of the peer review

process is to help to remove the bias. Even if there is, I mean I think that researchers tend to like the area they're focused on, and so you can't inherently remove all bias, but the point of peer review and why it's so important is to effectively have some scientific guardrails against bias clouding the actual results.

BY MR. WENIK:

Q When you're doing your peer review as a journal peer reviewer -- and you mentioned I believe you do it for a number of different journals -- is one of the things that you're looking at the funding of the research that's been submitted?

A It factors in, yeah. They have to disclose that.

Q And how does that factor into your analysis or review of the research?

A Well, it leads you to -- oftentimes in peer review you'll look at other references that are related, so it prompts you to look at either a body of work or a history of work or a focus of work.

Q And does the fact that a piece of research that you're peer reviewing is funded by a company, does that make it, in your view, scientifically invalid or worthy of less respect or worth?

A It could. Again, it's case by case. It depends on what gets presented.

Q And is it, in your mind, inappropriate for the organization that's funding research to comment on the research as it's being performed?

MR. SCOTT: Object as to form.

THE WITNESS: Again, it's case by case. In some instances that may be true. In other instances it may not be. It depends on a lot of factors.

BY MR. WENIK:

Q When you were a peer reviewer, have you seen where the sponsors of research have commented on the manuscript, edited the manuscript?

A Yes.

Q Does that in and of itself detract from the validity of the research in your mind?

A It has in some instances. In other instances it hasn't. It depends again on -- it's

case by case.

Q Is it inappropriate for the sponsor of research to have a role in which methodologies are employed in conducting the research?

MR. SCOTT: Object as to form.

THE WITNESS: It can. It certainly can. Again, it's case by case.

BY MR. WENIK:

Q So some cases yes, some no?

A Yes.

Q Now, when you're reviewing peer-reviewed research that's submitted to you, do you expect the researchers to submit to you all the data that they found, including the data that does not agree with their hypothesis?

MR. SCOTT: Object as to form.

THE WITNESS: Again, I think it depends on -- it's case by case. It depends on what they're reporting and what the study is. If it's, you know, something that requires that level of specificity, most certainly, or there should be a way to access supplemental files, which has been my experience as a peer reviewer. So if there's

supplemental information that generally is available, that usually satisfies most of the questions. However, you know, it's case by case.

BY MR. WENIK:

Q Would you consider it a breach of the scientific method for a researcher to exclude from his or her manuscript only that data that disagreed with his hypothesis?

MR. SCOTT: Object as to form.

THE WITNESS: Again, I think it's case by case. Depends on the study. I can envision scenarios where you wouldn't necessarily include everything, and I can envision scenarios where you want to include everything.

BY MR. WENIK:

Q When you published peer-reviewed articles, did you submit all the data of your findings to the peer reviews?

A Sometimes yes, sometimes no. Sometimes it wasn't, at least in our opinion, essential and necessary for the publication.

Q Did you ever engage in a process where

you selectively excluded only information that disagreed with your hypothesis?
A I'm not sure I understand the question.
Q You said that sometimes you would say some information would not be essential; is that right?
A Yes.
Q All right. Would you deem information not being essential only that which disagreed with whatever hypothesis you had for your research?
A Again, it's case by case. It depends on what the hypothesis is. If the hypothesis is so broad, you may not need every piece of information there. So again, it's case by case. It depends on the scenario.
Q Would you consider it an act of scientific dishonesty to falsify the results you published in a -- that one published in a peer-reviewed paper?
A Yes.
Q Would you consider it an act of scientific dishonesty to present a PowerPoint presentation at a conference that contained falsified information?

A Yes.
Q Do you know an individual named Amy Eichner?
A I know of Amy, yes.
Q Who is Amy Eichner?
A She works for the U.S. Anti-Doping Agency.
Q And what is your understanding of what her position is with that organization?
A She's a research chemist.
Q And during your tenure at the FDA, during that February of 2011 to April of 2014 period, did you have interactions with Ms. Eichner?
A We saw her at national meetings, and she liked to send us emails.
Q And what would be generally the subject matters of her emails to FDA?
A As many people do, they, you know, people -- FDA I like to describe as a big slow moving target that bleeds when you hit it, so people tended to want to give FDA their opinions of what they thought FDA's priorities should be, and Ms. Eichner engaged in that sometimes.

Q Did she in particular send you emails about what her opinions were regarding DMAA?
A I believe she did.
Q What is the relationship, if any, between the FDA and the U.S. Anti-Doping Agency?
A Other than we both get our funding from Congress, none.
Q Did officials of the U.S. Anti-Doping Agency attend any policy meetings at the FDA?
MR. SCOTT: Object as to form.
THE WITNESS: Would you elaborate on what you mean by "policy meetings"?
BY MR. WENIK:
Q Well, let me make it broad. Did they attend any meetings at the FDA, to your knowledge, U.S. Anti-Doping officials?
MR. SCOTT: You're talking about when he was there?
BY MR. WENIK:
Q Yes.
A I believe there was a public hearing on some Food Safety Modernization Act rules that they may have attended.
Q Did they attend internal FDA meetings

during your tenure?
MR. SCOTT: Object as to form.
THE WITNESS: No.
BY MR. WENIK:
Q Did you have teleconferences with Ms. Eichner during your tenure at the FDA?
A I spoke with her on the phone a number of times.
Q Did you speak with her about DMAA?
A Can you clarify a little bit?
Q Did she speak to you about her concerns about DMAA?
A Sure.
Q And was one of her concerns that DMAA posed a health risk?
A Mm-hmm, yes.
Q And were you aware of public speeches that Ms. Eichner was making in 2011 and 2012 regarding the purported dangers of DMAA?
A Yes.
Q So I'd like to turn your attention to -- I'm going to get the title right -- the National Center for Natural Products Research at the University of Mississippi.

Is this an entity that you're familiar with?

A Yes.

Q How are you familiar with this entity?

A There was money earmarked, technically -- you can't call it earmarked anymore -- by Senator Thad Cochran that established that as a center of excellence for FDA, and there was pass-through money given every year that FDA administered to the National Center for Natural Products Research that I was in charge of. I was the program officer.

Q Let me show you an email.

(Exhibit 3 was marked for identification.)

BY MR. WENIK:

Q Okay. Dr. Fabricant, I've put before you an email chain that I marked as Fabricant Exhibit 3, but before I even get to the email chain, I should lay a couple of foundational questions for it. So we've been talking about --

MR. SCOTT: Let me raise an issue here. I don't think this is my document. This confidentiality designation, the

numbers I can go double-check, but I believe this is designated by the University of Mississippi.

MR. WENIK: My understanding is that James Harlow and (person) at the University of Mississippi jointly designated certain things as confidential.

MR. SCOTT: My understanding was that, no, we went through and looked at things that were privileged, but the designations were from the University of Mississippi. We did not designate it confidential. So this is Mississippi's document. They designated it confidential, so I have no right to agree that you can use it on the record, because there's confidentiality on it. This is not something that I can deal with at the end, because it's not my document.

MR. WENIK: You want to pose an objection to its use?

MR. SCOTT: I guess I have to, because the protective order is in place, and unless you cleared it with them, I think it's

in violation of the protective order.

MR. WENIK: Well, it's a violation if it goes to the public.

MR. SCOTT: Well, it's a violation to use it. Dr. Fabricant is not under the protective order.

MR. WENIK: Well, if he's part of FDA.

MR. SCOTT: He is not part of FDA at this point in time. He's a former employee.

MR. WENIK: Well, you have your objection.

MR. SCOTT: I have my objection, and I'll have to let Mississippi know that this has been used in here, and they can take whatever action they want, but this is not my document. That's my point. Not my designation. I can double-check that, but I'm pretty sure that's -- I'm almost positive that's the case.

MR. WENIK: All right. Fair enough.

THE WITNESS: Should I answer the

question?

BY MR. WENIK:

Q I didn't ask you anything yet.

A I'm not on the protective order. I don't want to get myself in any trouble.

MR. SCOTT: I don't want to get myself in trouble either by allowing the witness to answer something that's -- let's take a break and let me check with James on the status of these things.

MR. WENIK: I think the protective order permits us to use these things at deposition but just not be filed in public.

MR. SCOTT: I think the order allows us to use things in deposition to the extent that they are presented to people who are covered by the protective order. For example, experts have to sign a designation saying they will comply with it.

MR. WENIK: Well, we can have Dr. Fabricant sign one.

MR. SCOTT: I don't think he qualifies under the protective order, because he's not a current employee and he's not an

expert, and there are certain categories of people who can and cannot access. That's why I want to get the protective order, check on the status of it, and then we'll go from there. Sorry to raise the issue, but I'm just not entirely comfortable with where we are at the moment.

(Whereupon, a short recess was taken.)

MR. SCOTT: We took a break so I could check the status of our document that's been marked as Exhibit 3. This is not a government-produced document. This was produced by the University of Mississippi.

Now, the University of Mississippi made the designations of confidential. We did not, and we did not have any input in that. That was solely theirs.

What we have done in coordination with them is review materials that they were producing to ensure they didn't turn over anything that was privileged based on the retention of Dr. Khan as an expert with us.

Now, under the protective order, as

a former employee, it's my reading that Dr. Fabricant would not be allowed to sign the protective order and be covered.

Now, having said that, for this document it's not an issue as I read it, because in section 3E, anyone who had access to the document prior to the litigation does not have to be signed up under the protective order. So for this document you can question the witness.

MR. WENIK: And similarly, I take it --

MR. SCOTT: If he's on them, yes. If he's not on them, I suggest your office call the University of Mississippi and work something out, because I'm hesitant to have him talk about documents that he should not have official access to under the protective order.

MR. WENIK: I hear you. I think everything I have is something you've already -- that your name is on it in some fashion.

MR. SCOTT: If that's the case,

then you're good.

BY MR. WENIK:

Q Okay. I'm glad we resolved that. So let me ask you a couple of foundational questions before I ask you to hook at that, Doctor.

So first of all, a gentleman by the name of Mahmoud ElSohly, is that somebody that you're acquainted with?

A Yes.

Q Is it your understanding that Dr. ElSohly is affiliated in one way, shape or form with the National Center for Natural Products Research?

A I was aware he was at the University of Mississippi.

Q And Ikhlas Khan, is Dr. Khan someone that you're acquainted with?

A Yes.

Q And is it your understanding that Dr. Khan is affiliated with the National Center for Natural Products Research at the University of Mississippi?

A Yes.

Q Okay. Now that I've asked those

questions, now I can turn my attention to Fabricant Exhibit 3, which is an email chain between Dr. Khan and yourself.

First of all, have you looked at this? Does this refresh your recollection of having had some email communications with Dr. Khan?

MR. SCOTT: Be sure you read the whole thing to understand the context.

THE WITNESS: Yes.

BY MR. WENIK:

Q And you mentioned before that there were some federal government monies that would be administered, for lack of a better word, by the FDA for the National Center for Natural Products Research.

Is that some of what's being referred to in the email chain here in Fabricant Exhibit 3?

A Yes. We were on a continuing resolution in 2012. The University of Mississippi was not on a continuing resolution and needed our budget numbers, as the two fiscal cycles didn't always coincide. So that's what this email refers to.

Q And they had to fill out some sort of -- I don't know -- grant proposal or other paperwork

to get their funding through you; is that right?
A There was a renewal process for the center.
Q Okay. So let me ask you just to interpret some of these things for me. I'm looking in the middle of it. You wrote to Dr. Khan, "yes, 300 from Diego plus 400 from us plus 1.6 as the base."
So this 1.6, would that be $1.6 million?
A Yes.
Q So the $1.6 million as the base, is that part of this FDA federal funding?
A Yes.
Q And 400, would that refer to $400,000?
A Yes, in supplemental money.
Q From the government, okay, and what is the 300 from Diego? What would that be referring to?
A Diego was the program officer at the Office of Cosmetics and Colors for University of Mississippi, so I was the program officer for the whole center, so they had some additional work that they had money set aside for at the University of Mississippi for research work.

Q I see. Okay.
Have you heard of an entity known as ElSohly Laboratories, Inc.?
A Yes.
Q What is your understanding of what that entity is?
A That it's a -- I guess there's a partnership with the university and Dr. ElSohly to conduct some, I guess, you know, to be semi-entrepreneurial, research-wise.
Q Did the FDA have any contractual relationships with ElSohly Laboratories, Inc.?
A No.
Q Do you know whether Dr. Khan had an ownership stake in ElSohly Laboratories?
A I don't know his -- I don't know the financial arrangements.
Q Are you familiar with another entity known as Phytochemical Services, Inc., or PSI?
A No.
Q And how about an entity known as ChromaDex; is that an entity that you're familiar with?
A Yes.

Q How are you familiar with ChromaDex?
A I've known Frank Jaksch, the founder of ChromaDex, since I was in graduate school, so for about 20 years. ChromaDex is a company on my current board.
Q And what is your understanding of what ChromaDex does?
A A lot of different things. Produce fine chemicals for food supplements, analytical testing services, standard development, to name a few things.
Q Does ChromaDex also manufacture dietary supplements?
A Ingredients.
Q Do they manufacture ingredients that are used in dietary supplements?
A Yes.
Q And was that true during your tenure at the FDA, that they manufactured ingredients for dietary supplements?
A I believe so.
Q Do you know whether Dr. Khan, Ikhlas Khan, has any role or position with ChromaDex?
A He worked on pterostilbene, and I

believe there was some technology-sharing between the University of Mississippi and ChromaDex.
Q Do you know whether Dr. Khan has an ownership stake in ChromaDex?
A I don't know what his financial arrangements are.
Q What is your understanding of what Dr. Khan's area of expertise is?
A Natural products research. He's world renowned, once of the best natural products scientists globally, phytochemistry to really spanning -- it's a multidisciplinary field, so spanning all those areas, and he's helped to establish University of Mississippi as really a leader in all those relevant areas.
Q Is his training as a chemist?
A Yes.
Q To your understanding, is he a clinician at all?
A No, but he's been involved in clinical studies.
Q And is he someone whose judgment you trust?
A Yes.

Q When you were at the FDA, is he somebody whose advice you sought out?

MR. SCOTT: Object as to form.

THE WITNESS: Amongst others, yes, scientifically.

BY MR. WENIK:

Q Would you feel he's a person of some integrity?

A Yes.

Q Let me ask you about Dr. ElSohly. What is your understanding of his area of expertise?

A Dr. ElSohly is a very well-respected chemist, is one of the world leaders in banned substance testing of marijuana, cannabinoid ingredients, amongst other natural products, and is very adept at natural products research and has been for some time. Still holds a faculty position at the University of Mississippi and is very well-respected.

Q Is he a clinician?

A No.

Q Is his training as a chemist?

A Primarily, yes.

Q And is he someone whose judgment you

trust?

A Yes.

Q Did you seek his advice when you were at the FDA?

MR. SCOTT: Object as to form.

THE WITNESS: I spoke with a lot of scientists, yes.

BY MR. WENIK:

Q All right. So let me ask you just generally: Would it be fair to say that you believe that DMAA poses a serious health risk?

MR. SCOTT: Object as to form.

THE WITNESS: Again, I think the evidence shows that DMAA is in violation of federal law, and given that DMAA behaves like an amphetamine, as it was previously under -- you know, as it was previously under an NDA to be sold as a drug, I'm unfamiliar with any drug that doesn't have side effects.

BY MR. WENIK:

Q But my question is: Putting aside the legality -- I understand your regulatory expertise. Do you feel as a scientist that this is something that poses a danger?

MR. SCOTT: Same objection.

THE WITNESS: I think putting drugs in the food supply is a danger.

BY MR. WENIK:

Q Okay. Is it your view that DMAA should be removed from the marketplace?

MR. SCOTT: Same objection.

THE WITNESS: DMAA, based on the letter of the law, based on the fact that it is a drug, shouldn't be available as a food.

BY MR. WENIK:

Q And was it your goal, when you were at the FDA, to have DMAA removed from the food supply?

MR. SCOTT: Object as to form.

THE WITNESS: My goal was to protect the public health, and any areas I saw as violative, to effectively enforce.

BY MR. WENIK:

Q And was one of the ways that you were seeking to protect the public health is to have DMAA removed from the food supply?

A DMAA was violative of the Food, Drug & Cosmetic Act, so I would not be dispatching my

duties if there were things that were violative that the agency wasn't taking appropriate action on.

Q So I take it your answer is yes, that this was something you wanted removed from the marketplace; you felt it violated the law, right?

A What I said -- I didn't say it felt anything. I said it violated the law, and so we took appropriate action. There's a process for that. We followed the process.

Q Is it your view that DMAA is not found in the geranium plant?

MR. SCOTT: Same objection.

THE WITNESS: Based on the evidence I've seen and the evidence we conducted and compiled at the agency, I think that again our understanding, based on that evidence, is that DMAA is not found in a plant.

BY MR. WENIK:

Q And when did you first come to that view, that analysis?

A Well, I think we looked -- we had an initial memo leading out to the first warning letters, which established the regulatory

questions regarding DMAA.

(Exhibit 4 was marked for identification.)

BY MR. WENIK:

Q Let me show you this document. I've placed before you a document that I've marked for identification as Fabricant Exhibit 4, which is an email chain and an attached brief news story. If you could take a moment to look through that, I want to ask you a quick question.

MR. SCOTT: Be sure to review it so you understand the context.

(Witness peruses document.)

THE WITNESS: Yes.

BY MR. WENIK:

Q All right. So from time to time when you were at the FDA, did you have contact with journalists?

A Yes.

Q And would one of those journalists be somebody who worked for a Tribune company?

A Yes.

Q So it appears that you wrote, back in July of 2012, "On DMAA, people were looking for

the next big thing post-ephedra. Patrick Arnold of BALCO fame played a role."

Do you see that?

A Yes.

Q What role, if any, do you think Mr. Arnold played in DMAA being out there for sale?

A To our knowledge, when I was at the agency, there were some blogs where he discussed it, going back to 2007, 2006, that mentioned DMAA and how it was, you know, the latest and greatest thing.

Q And what did you mean in this email by "the next big thing post-ephedra"?

A That was I believe from -- one of my people looked at those blogs, and those were the words of Mr. Arnold.

Q Okay. Was it your understanding at this time that DMAA was being -- well, withdraw it.

(Exhibit 5 was marked for identification.)

(Exhibit 6 was marked for identification.)

BY MR. WENIK:

Q Doctor, I've placed before you two documents that I've marked for identification as Fabricant Exhibit 5 and Fabricant Exhibit 6. Fabricant Exhibit 5 is a copy of --

MR. SCOTT: Jack, this one has got highlighting on it.

MR. WENIK: That's all right.

MR. SCOTT: Okay.

BY MR. WENIK:

Q Fabricant Exhibit 5 is a copy of an April 24, 2012 warning letter to USPlabs, and Fabricant Exhibit 6 is a copy of an April 18, 2013 letter to USPlabs.

So my first question to you is: Just looking at Fabricant Exhibit 5 for a moment, have you seen that document before, this warning letter?

A Yes.

Q All right, and were you involved in the preparation of this warning letter?

A Yes.

Q How were you involved in the preparation of this warning letter?

A We wrote the expert memo and obviously discussed with the Office of Compliance and the Office of Chief Counsel aspects of the letter and the memo.

Q And was this something that you approved of its dissemination, this letter?

A Yes.

Q Okay, and then this letter here, the one I marked as Fabricant Exhibit 6, which is a letter dated April 18, 2013, my questions were -- well, first of all, have you seen this letter before?

A Yes.

Q And were you involved in the drafting of this letter in any way, shape or form?

A Yes.

Q And how were you involved in this letter?

A Similar. We prepared the expert memo underneath it and worked with -- there's a process at FDA to work with the Office of Chief Counsel and Office of Compliance to ensure that things are accurate and consistent with FDA's authorities.

Q All right, and I'm looking at Fabricant Exhibit 6, and the first sentence of this letter

to USPlabs, it says that "We acknowledge receipt of your letters dated May 15 and 17, 2012, September 28, 2012, and January 14, 2013, which respond to the April 24, 2012 FDA warning letter issued to your firm."

Do you see that?

A Yes.

Q And my question to you is: So the letters that USPlabs, that are referred to here that responded to Fabricant Exhibit 5, at some point when you were at the FDA, did you see those letters, the USPlabs response?

A I saw their responses, yes.

Q Okay.

(Exhibit 7 was marked for identification.)

BY MR. WENIK:

Q Doctor, I've placed before you a document that I've marked for identification as Fabricant Exhibit 7, which is five pages. I'll describe it -- for lack of a better term, it looks like talking points. If you could take a moment to take a look at this. Then I'm going to ask you a couple of questions.

(Witness peruses document.)

THE WITNESS: Okay.

BY MR. WENIK:

Q All right. So I'm looking at page 4 of this document, and there's a bold question. It says, "Didn't you lobby for industry to weaken these authorities in your previous position?" And it says, "When I ran the Natural Products Association, the big part of my job was to push our members for greater compliance with the laws, because consumers deserve safe products."

So my question is: Having looked at that excerpt and looked at this document, is this something that you've seen before?

A I believe I have. It was developed I believe by our press office at FDA.

Q Did you have a role in helping to create this document?

A Yes, somewhat, but it was still by our press folks to be responsive to incoming inquiries.

Q And did you review the talking points from the press office?

A I don't know if this is the final

version or not. I mean I'm sure I reviewed it, but again not knowing if this is the final or not, obviously I wouldn't -- you know, what's here versus what may be in the final may be different with my changes.

Q Okay. Fair enough.

So I'm looking at the first page of the document, and it says, "One company [USPlabs] submitted a response to our warning letter, including studies purporting to show that DMAA is a dietary ingredient. However, FDA's review found this information insufficient. FDA is finalizing a formal response to the company regarding the additional information its lawyers submitted following the FDA's warning letter."

Do you see that?

A Mm-hmm, yes.

Q So would it be fair to say that the talking points are referring, when it says "FDA is finalizing a formal response," that they're referring to what ultimately became Fabricant Exhibit 6, this April 18, 2013 letter, that that was the formal response to USPlabs' letters?

A It may have been earlier in the process.

Again, not knowing if this is the final or not, I don't know that this bullet would have necessarily stayed in a final version. It wasn't generally our policy to discuss what was happening behind the scenes, you know, for a variety of reasons. So if you want me to speculate and say it's referring to this one, sure, but we got --

Q I guess my real point is -- would it be fair to say that this document, the bullet points, were prepared at some point in time prior to April 18, 2013, prior to when the response went out?

A Just because they were prepared, again I don't know if this is -- I don't think this is the final version, so just because somebody wrote something down on a piece of paper doesn't mean they were, you know, it was the -- again, this is, this looks like a draft, if anything.

Q All right, but you would agree with me, whether it's a draft or not, it was prepared before this letter?

MR. SCOTT: Object as to form.

THE WITNESS: Again, not, not having the dates. It could have been.

BY MR. WENIK:

Q Okay. Let me ask you to take a look at page 2 of the Fabricant Exhibit 7, and I'm looking at the third bullet point down from the top, and it says, "DMAA has known pharmacological effects on the human body -- it can narrow blood vessels and arteries."

So let's take that first statement. Is that something that, based on the information that you've seen that you believe is true, that DMAA can narrow blood vessels and arteries?

A That's the information based on Forthane's NDA when Forthane was used as a drug.

Q So that would be the factual basis for that statement, the Forthane NDA?

A Yeah, I mean that's a known pharmacological effect on the human body.

Q Okay, and then it says "which can elevate blood pressure." Is that something, is that statement something that, based on what you've read, you believe is true?

A If it narrows blood vessels and arteries, that elevates blood pressure.

Q And then it says "can lead to

cardiovascular problems ranging from shortening of breath and tightening in the chest to heart attack."

That last phrase, is that something, based on what you've seen, that you believe is true?

A Well, again, that's the pharmacology of what was submitted for Forthane. If you have an elevated blood pressure, that, of course, can lead to any of those. You know, that's what it says right here. If you elevate blood pressure, that can lead to cardiovascular problems, ranging from shortening of breath, tightening of the chest, to a heart attack. That's not a secret.

Q Are you aware of any clinical studies showing DMAA causing heart attack?

A We generally don't do clinical studies on people, since World War II, to show that something kills them. There are a lot of really good laws against that.

Q Are you aware of any epidemiological studies showing that DMAA causes heart attack?

A I think there's a variety of case reports, but I'm not speaking to the case reports

that are out there on DMAA's safety for this particular . . .

Q So the basis for saying that it could lead to heart attack would be the case reports and the NDA materials for Forthane?

A Well, the NDA materials, that was by the people who made Forthane. That was one of their side effects, so yes.

Q Let me direct you to the last three bullet points on page 2.

So I'm looking at the third one from the bottom. It says, "The law does NOT give FDA pre-market approval to determine whether or not dietary supplements are safe or effective prior to marketing, unlike the laws for marketing drugs."

Is that something you agree with?

MR. SCOTT: Object as to form. Calls for a legal conclusion.

MR. WENIK: He did say he was a regulatory expert.

MR. SCOTT: I didn't direct him not to answer.

BY MR. WENIK:

Q Go ahead.

A The law doesn't give FDA pre-market approval. It's a notification system.

Q And then you wrote, "In most cases, companies do not even have to tell us about a product prior to selling it. The law only requires companies to notify FDA when they intend to market a dietary supplement containing a New Dietary Ingredient (NDI) in the United States, if the NDI has not been used in the food supply in the same chemical form."

Do you agree with that statement?

MR. SCOTT: Same objection.

THE WITNESS: As it pertains to NDIs, yes.

BY MR. WENIK:

Q "An NDI is a dietary ingredient that was not marketed in a dietary supplement prior to October 15, 1994."

Do you agree with that?

A Yes.

Q Then the second bullet from the bottom there, it say, "Under current law, manufacturers of dietary supplements are not required to prove the safety and efficacy of their products to FDA

prior to marketing."

Is that a statement you agree with?

MR. SCOTT: Same objection.

THE WITNESS: Yes.

BY MR. WENIK:

Q And the last bullet there says, "To ban a dietary supplement, FDA must clearly demonstrate that the product is adulterated (e.g., because it contains an unsafe food additive or presents a 'significant or unreasonable risk' when used as directed the label)."

Is that a statement you agree with?

MR. SCOTT: Object as to form.

THE WITNESS: Yeah, and these are talking points that were created by someone in the press office. I would have, I would have worded things slightly different. I think they kind of have the concept down.

BY MR. WENIK:

Q And it says, "This process can take years."

Do you agree with that, that it could take years to formally ban an ingredient?

A That's from the agency's experience.

However, that's specific to things that are dietary ingredients. They would have to be a dietary ingredient for the FDA to ban it. If it's not a dietary ingredient, well, then it doesn't belong in the food supply to begin with.

Q Was it your belief, during your tenure at the FDA, that the FDA needed enhanced regulatory tools to conduct its mission regarding dietary supplements?

A I didn't have an opinion. I was there to execute the authorities I did have.

Q What is your opinion today as you sit here, part of the Natural Products Association? Do you think the FDA needs additional regulatory tools to deal with dietary supplements?

A By and large, I think the laws are there, and they can certainly be used appropriately.

Q Was it your position when you were in the FDA that geraniums were not in the food supply prior to October 15, 1994?

A I have --

MR. SCOTT: Let me object as to form.

To the extent that you can answer the question based on public positions that have been taken by FDA, please do so, but if there are any -- if you have any information that's based on internal discussions that were not made public, then I direct you not to answer on that basis, based on the deliberative process privilege.

THE WITNESS: Based on our findings -- we obviously researched that question. In terms of for a dietary supplement, geraniums did not appear to be on any of the grandfather lists in terms of being sold as a dietary supplement. Rose geranium oil we were familiar with as a food additive, which was pre-'94.

BY MR. WENIK:

Q All right. So just looking at this document as a reference point, for lack of a better word, Fabricant Exhibit 5, prior to April 24, 2012, prior to the issuance of that warning letter, were you made aware of the death of a military serviceman that was possibly linked to DMAA?

A Yes.

Q And in the wake of that serviceman's death, were there news accounts about that incident?

A Yes.

Q And did you feel pressure from news media accounts to take some action regarding DMAA in the wake of those news reports regarding the death of this serviceman?

A I think that's two questions.

Q All right. Did you feel pressure from the media to take action against DMAA?

MR. SCOTT: Object as to form.

THE WITNESS: Yeah, that still seems like two questions.

BY MR. WENIK:

Q You were aware of the news reports regarding the serviceman's death; is that right?

A Yes.

Q Did those news reports in part encourage you to take action against DMAA?

A No.

Q Did individuals encourage you to take action against the DMAA from the public?

A Outside of FDA?
Q Yes.
A No.
Q Were you receiving industry exhortations to take action against DMAA?
MR. SCOTT: Object as to form.
THE WITNESS: Sure. However, the fact remains. It was our burden to build a case, and we had a system, we worked the system, and this was -- you know, we had a variety of NDIs that we took action against.
BY MR. WENIK:
Q Are you familiar with a Harvard researcher named Pieter Cohen?
A Yes.
Q What is your familiarity with Dr. Cohen?
A Dr. Cohen was a friend of the former deputy commissioner, Joshua Sharfstein, while I was at FDA, and I met Dr. Cohen through Dr. Sharfstein.
Q Did you have conversations with Dr. Cohen about DMAA?
A I did.
Q Did he urge you to take action against

DMAA?
A That was his opinion. A lot of people had opinions on DMAA.
Q Is it your opinion that he's a reputable scientist?
A Sometimes.
Q I have to probe on that. At what times would you believe that Dr. Cohen is not a reputable scientist?
A Look, he has an opinion. He feels he can be an advocate for public health by getting his opinion out. I don't always agree with that. However, he is, you know, reputable in terms of -- the actual science he does is very reputable.
Q Did his writings or opinions influence the actions you took regarding DMAA?
A No. We have a process at the agency. We worked the process.
Q Let me ask a couple more questions, and then we'll take a break.
So take a look at Fabricant Exhibit 5 for a moment, if you don't mind, and look at the second page, and I'm looking at the first paragraph from the top there. It says, "To the

best of FDA's knowledge, there is no information demonstrating that dimethylamylamine" -- which we call it "DMAA," correct --
A Yes.
Q -- "was lawfully marketed as a dietary ingredient in the United States before October 15, 1994, nor is there information demonstrating that this ingredient has been present in the food supply as an article used for food in a form in which the food has not been chemically altered."
Do you see that?
A Yes.
Q At the time this letter was written back in April 2012, what is your recollection of what the factual bases were that supported that statement in the letter?
A We had a memo that looked for -- that established whether or not it was, based on the sources we had, whether or not it was in the diet. We couldn't search an unlimited universe, but we searched a pretty extensive universe, and that was what we established.
Q When you say you were searching, were you searching for DMAA as that substance, were you

searching geraniums, or both?
A We searched as DMAA, we searched as the other names of DMAA that were being used. And specific to the law, DMAA was the article in the diet, not geraniums, or at least that's what USPlabs was supposing.
MR. WENIK: All right. Why don't we take a break, because we've been going now for a while. Stretch your legs, use the restroom.
(Whereupon, a short recess was taken.)
(Exhibit 8 was marked for identification.)
BY MR. WENIK:
Q Doctor, I placed before you a document that I've marked as Fabricant Exhibit 8, which is a document that was originally marked by the government at another deposition, and you'll see the first few pages are in a foreign language, and then there's a certified English translation of it that follows.
And the document purports to be a memorandum from the DTU National Food Institute,

which is a university in Denmark is my understanding of what DTU is.

My simple question to you is: Is this something that you've seen before?

A I believe I have.

Q And did you have this information at the FDA at the time that Fabricant Exhibit 5 was prepared, that kind of warning? Was this one of the things that went into the basis for that letter?

MR. SCOTT: Well, let me object and ask for clarification. Are you talking about the Li document? The translation is dated August of 2016.

BY MR. WENIK:

Q Right. I assume you didn't have this particular translation, but my question is: Did you have some version of this, I guess is the better question, when you put out this warning letter?

A I would have to see our memo, but I think -- again, I'd have to see the memo to refresh for certain that we had -- again, I'd have to see the memo for certain. It's all the

references we had on the initial, for the initial warning letter. This was one of them, so . . .

Q Okay. Was it the practice when you were at the FDA that you would look at information from abroad in making decisions?

A We'd look at -- again, we'd search a variety of scientific information. You know, you can never get the whole universe, but we tried to get as much of it as we could. Yeah, if there were papers, foreign papers, they certainly would -- we'd look at them.

Q Okay, and how much weight would you give to information from a foreign entity?

MR. SCOTT: Object as to form.

THE WITNESS: As with any reference, it's case by case. It depends on the quality of the work done. It depends on, you know, the scientific rigor there. It depends on a variety of things. Is it peer-reviewed? Is it -- you know, what is it?

(Exhibit 9 was marked for identification.)

BY MR. WENIK:

Q Doctor, I've placed before you a document that I marked for identification as Fabricant Exhibit 9, and I'd ask you to take a moment or two to take a look at it. It's an email chain from May 11, 2011.

A Okay.

Q Have you seen this email chain before?

A Looks like I was copied on it.

Q All right. Do you know Philip Gregory?

A I've met Philip before, yes.

Q Who is Philip Gregory?

A He is the editor or creator of Natural Medicines Database.

Q And what is your understanding of what the Natural Medicines Database is?

A It's kind of an electronic newsletter. It goes to health practitioners on dietary supplements.

Q All right, and Patricia Deuster, are you familiar with this individual?

A Yes.

Q Who is Patricia Deuster?

A She was a professor at UUHS, the

University of Uniformed Health Services.

Q All right, and what is the relationship, if any, between the FDA and this university?

A Formally? We had a -- as we have the, uh, the Public Health Service, so there's a formal MOU, memorandum of understanding that, where appropriate, some information can be shared, but it has to go through -- there was a program officer for that at White Oak.

Q All right, and this particular email talks about there being a report in the literature of a "positive urine drug screen for amphetamine and related substances in a patient taking this ingredient. DMAA has structural similarities to amphetamine," and then there's a citation to an article called "Dimethylamylamine: A Drug Causing Positive Immunoassay Results for Amphetamines." Then there's a citation for a journal.

Do you see that?

A Yes.

Q That citation, that article, was that something that you recall was looked at prior to the issuance of this warning letter that we have as Fabricant Exhibit 5?

A It may have been. Again I'll have to see the memo and see everything that was cited there. We always list what we cite.

Q And what's the significance in your mind of there being a positive screen for amphetamine perhaps caused by DMAA? What significance does that have for you?

A Well, it would be, you know, for war fighters or for police officers or people like that, firefighters, you know, a false drug test that's, you know, that would be it, that if they got a drug test for this, for using amphetamines when they didn't use amphetamines, that would be the extent of it.

Q Does that in and of itself raise any sort of safety concern to you, the fact that it may react to an immunoassay for amphetamines?

A No. We already had the data from the Forthane submission at the agency before May 11, so it's, again, it's a data point, but it's not one that I think is -- you know, there were stronger data points.

Q And would you agree with me that DMAA is something distinct and not the same as

amphetamine?

MR. SCOTT: Object as to form.

THE WITNESS: DMAA has some characteristics -- it's not methamphetamine, but it has some characteristics -- you know, it's a bronchodilator, a vasoconstrictor. Amphetamines do that as well, so it has some pharmacological functions like an amphetamine, but is it methamphetamine? No.

BY MR. WENIK:

Q Amphetamines and DMAA are two separate things, correct?

MR. SCOTT: Object as to form.

THE WITNESS: Again, we just talked through how some of them are related, how some of the pharmacological actions are related, vasoconstriction, bronchodilation. Those are related physiologically, so it displays some characteristics, and I think, you know, like I said, it's not methamphetamine, but it displays some characteristics of the class of compounds we know as amphetamines, and the structural -- the structure is similar.

BY MR. WENIK:

Q Similar but not the same?

MR. SCOTT: Same objection.

THE WITNESS: It's not the same as methamphetamine.

BY MR. WENIK:

Q Different molecule? Different molecular structure, rather?

A Than methamphetamine, yes.

(Exhibit 10 was marked for identification.)

BY MR. WENIK:

Q Doctor, I've placed before you a document that is marked for identification as Fabricant Exhibit 10, which appears to be an email chain between you and Corey Hilmas, amongst others, and if you could take a moment to look through it, I'll ask you a couple of questions.

A I don't think it's an email chain. It's just me sending a document to Corey that somebody sent me.

Q Correct.

A So that's different. There's no --

Q No, I didn't mean to suggest that you

drafted the email. It's something that you forwarded on. Let's just describe it that way. That's fair.

So my question to you is: Looking at it, it says "from Daniel Fabricant" --

MR. SCOTT: Are you finished reading it?

THE WITNESS: Yes.

BY MR. WENIK:

Q To Corey Hilmas, so we've discussed already who Corey Hilmas is.

Who is Ramadevi Gudi?

A She was the acting lead for the New Dietary Ingredient review team at that time.

Q Okay, and the subject line, I take it, is something that you drafted. "Forward: More data on Forthane/DMAA safety and DRUG data from the literature."

Is that right?

A No, I didn't draft that at all. It came from this email which I forwarded.

Q So you just copied the --

A I just forwarded it to my people.

Q Okay. James Neal-Kababick; do you know

who that is?
A Yes.
Q Who is James Neal-Kababick?
A He runs a lab called Flora Research.
Q And what does Flora Research do?
A They do a variety of testing in the dietary supplement industry.
Q And what is your understanding of Mr. Kababick's area of expertise?
A Analytical laboratory expertise, looking at, you know, looking at a variety of compounds that are out there.
Q All right. Is this somebody that you knew from your days at the NPA prior to going to the FDA?
A I think I first met Jim when I was in graduate school at University of Illinois.
Q Was he studying at the same institutions you were?
A No, but some of the meetings, there were overlaps. The American Society of Pharmacognosy, the American Chemical Society, things like that. There was some overlap.
Q Okay. What's your understanding of

Mr. Kababick's training, if any?
A He, you know, is a chemist is my understanding of his training.
Q Is he someone whose views you respect?
A I mean his lab has been around a while, so I think, you know, he certainly has, seems to, you know, seems like -- I mean I don't think any one analytical lab does everything perfect, but he seems to do a good job.
Q Does the information that you forwarded on here, is this information you considered in thinking about DMAA when you were at the FDA?
MR. SCOTT: Object as to form.
THE WITNESS: Yeah, I'm not sure what you're asking, because some of this information we already had. It was just a -- again, I would get a lot of these things, and I wanted to make sure we kept a file on them.
BY MR. WENIK:
Q So I take it you reviewed what he said?
A I read it, yeah, but again it's nothing we didn't already know from what was in -- you know, what FDA already had available to it.
Q Okay. On the second page of this

document, he talks about "I can only hope that FDA is drawing back the bowstring on this and not ignoring what I think is a blatant attempt to sell yet another pharmaceutical drug dressed up as a dietary supplement."
What was your understanding of what were the other pharmaceutical drug he was referring to there, your understanding, if you recall?
A No idea.
MR. SCOTT: Object as to form.
THE WITNESS: Yeah, you should ask Jim.
BY MR. WENIK:
Q Oh, I will. We will.
His deposition already took place?
MR. SCOTT: Yes, last Friday.
MR. WENIK: We probably did already.
BY MR. WENIK:
Q He wrote further on here, "I completely support Health Canada's position on this and their evaluation of the Ping paper."
Do you see that?
A Yes.

Q What is your understanding of what the Ping paper was?
A Well, we evaluated the Ping paper in our first memo. It was a paper from '96 in a journal that I think is defunct, and from a researcher that no one has ever met, describing the presence of DMAA in geranium.
Q All right, and would it be fair to say that at the time that the April 24, 2012 warning letter went out, that you did not believe that there was evidence of DMAA being present in geraniums?
A Based on what we had seen and working through the process the way we had -- and again I believe you have that memo predating that. That's all laid out there. We followed the process and we moved ahead.
Q But following the process, you didn't think that there was DMAA in geraniums at that time; is that right?
A Well, the evidence suggested that DMAA was likely not from geraniums. Again, that's why we send the warning letter. This is a final agency action. It says if there is information

available, they can provide it. USPlabs did on a number of occasions, and it didn't rise up to the level.

Q These old textbooks that Mr. Kababick cites here, you believe that you had the benefit of that information, the original source material?

MR. SCOTT: Object as to form.

THE WITNESS: I don't think it would have gotten to or through the agency without that material, yes.

BY MR. WENIK:

Q Did you have conversations with Mr. Kababick about DMAA?

A A lot of people wanted to talk about DMAA, okay? Just because people have an opinion doesn't, you know, doesn't shape the agency's actions.

Q Right, but my question is: Did you have conversations with him about DMAA?

A I had conversations with people about a lot of subjects.

Q Including Mr. Kababick?

A Yes.

(Exhibit 11 was marked for identification.)

(Exhibit 12 was marked for identification.)

BY MR. WENIK:

Q All right, Dr. Fabricant, I've placed before you two documents that I marked for identification as Fabricant Exhibit 11 and Fabricant Exhibit 12.

For the record, Fabricant Exhibit 11 is an email between Patricia Deuster and a number of recipients, including you, and Fabricant Exhibit 12 is a document from Health Canada regarding DMAA.

So my first question to you is: Looking at Fabricant Exhibit 11, that document, have you seen this before, this email before?

A I was copied on the thread.

Q All right, and Patricia Deuster is telling you that Health Canada has decided to classify DMAA as a drug.

Do you see that?

A Yes.

Q Is it your understanding that what she

was referring to in this August 2, 2011 email was what I put before you as Fabricant Exhibit 12, that that was the decision of Health Canada?

A That's what she sent around.

Q All right, and this document, the decision of Health Canada, is this something that was considered by your division within the FDA at the time that Fabricant Exhibit 5, this warning letter, was being prepared?

A We had a preliminary -- we had a few preliminary calls. We had an information-sharing arrangement with Canada, the FDA does, and so we had discussed it a number of times, and I think we had a draft memo long before this, and some of their references as well.

Q "Long before this" meaning Fabricant Exhibit 12? You had a draft memo from Canada before this?

MR. SCOTT: Exhibit 12 is the document from Canada. A draft of that?

MR. WENIK: I think that's what he said. That's why I'm trying to clarify.

MR. SCOTT: Oh, okay.

THE WITNESS: We had conversations

regarding it leading up to this, you know, bound by that arrangement with Health Canada. We were familiar with this prior to this.

BY MR. WENIK:

Q Prior to Fabricant Exhibit 5?

A Yes.

Q All right. So let's look at the Health Canada document for a moment if you don't mind. So the second page under the discussion section, it says, "DMAA is used in party pills," and my question is:

At the time that your agency was considering writing this April 24, 2012 warning letter, Fabricant Exhibit 5, did you have any information about DMAA being marketed as "party pills" in the United States?

A We had seen some reports that it was used as such.

Q In the United States, reports of it being used as such in the United States as opposed to other countries?

A We saw it from other countries, if memory serves, but again I'd have to look at all of our documents that went into the memo behind

this, but we had, we had heard that that was one possible use of it.

Q All right, and it says further on in the third line, it says, "DMAA is included on the World Anti-doping Agency's prohibited substance list as a stimulant."

Do you see that?

A Yes.

Q So my question to you is -- and you mentioned before your regulatory expertise -- because a substance is banned by an anti-doping agency, does that fact in and of itself make it not a dietary ingredient?

A No, that wasn't what made it not a dietary ingredient.

Q And the fact that something is banned by an anti-doping agency, does that in and of itself mean that a substance is unsafe as opposed to conferring some competitive advantage?

A No. Again, DMAA, our findings and based on this memo were it wasn't in the plan, based on what we found.

Q Right, but let's step back for a minute from DMAA.

The fact just generally that something is banned by an anti-doping agency, that in and of itself doesn't mean that the entity is unsafe, does it?

A No.

Q Would you agree with me that the Canadian government has a different regulatory scheme for drugs and foods than the United States does?

A Yes.

(Exhibit 13 was marked for identification.)

(Exhibit 14 was marked for identification.)

BY MR. WENIK:

Q So, Doctor, I've placed before you a document that I marked for identification as Fabricant Exhibit 13, which for the record is a -- I downloaded it from the FDA's archive content on their website, an April 27, 2012 press release, and Exhibit 14 appears to be the same document that you emailed to yourself back in April 27, 2012, or maybe it was on your system back on April 27, 2012.

Do you see that?

A Yes.

Q All right. So my question to you is: First of all, have you seen these documents before?

A Yes.

Q All right, and what is your understanding of what they are?

A They are a press announcement regarding the ten warning letters that went out on DMAA.

Q Okay. Did you have a role in helping to draft the press announcement regarding the warning letters that went out on DMAA?

A Yes.

Q What was your role in doing that?

A Obviously we provided the expert memo underneath that to the press office and worked with them on drafting it.

Q Okay, and I'm looking at Fabricant Exhibit 14, just because it's not cut off. It says, "'Before marketing products containing DMAA'" -- I'm looking at the second paragraph from the bottom -- "'manufacturers and distributors have a responsibility under the law to provide

evidence of the safety of their products. They haven't done that, and that makes the products adulterated,' said Daniel Fabricant, Ph.D., director of the FDA's Dietary Supplement Program."

Do you see that?

A Yes.

Q Did you approve of that statement going into the press release?

A Yes.

Q All right.

If we look at the warning letters or rather the list in the press release of the warning letters, it does not include under the list of companies Hi-Tech Pharmaceuticals, does it?

A No.

Q Okay. So Hi-Tech is not here, and neither are any Hi-Tech products listed here, are there?

A No.

Q Let me rephrase that.

Would you agree with me that Hi-Tech Pharmaceuticals is not on the list of companies in the press release?

A Yes.
Q Would you agree with me that the press release doesn't list any Hi-Tech products?
A Yes.
Q Okay. Do you believe the press release is accurate?
MR. SCOTT: Object as to form.
THE WITNESS: Yes. It talks about the actions that were taken by the agency.
(Exhibit 15 was marked for identification.)
BY MR. WENIK:
Q So, Dr. Fabricant, I've placed before you a document that I've marked for identification as Fabricant Exhibit 15, which looks like a news article that's been incorporated into an email chain back on April 27 of 2012.
Do you see this?
A Mm-hmm, yes.
Q And are you in the email chain, your name?
A Yes, I am.
Q Are you familiar with an individual known as Steve Mister?

A I am.
Q How do you know Mr. Mister?
A He is the CEO of the Council for Responsible Nutrition.
Q And what is the Council for Responsible Nutrition?
A It is a supplement trade association.
Q And that's something distinct from separate from the Natural Products Association?
A They are separate. I'd like to think that, yes, we are very distinct. They tend to represent more of, more of MLM type companies, multilevel marketing, not necessarily as involved in retail as my organization.
Q All right, and look at the second page of the document, and at the bottom third of the page, there are some quotations from Mr. Mister, and he says, amongst other things, that "'The CRN has no vested interest in DMAA,' he said, but added: 'We've always said we don't want to rush to judgment on this. The science of this has to play out, and hopefully this is now an opportunity for the companies listed to give us some more clarity.'"

And then further on there's a quote from him. "I don't see this as a black and white issue. There are many shades of gray."
And in the email chain you said that, quote, "Can you believe Steve Mister? What a putz!"
My question to you is: Putting aside the translation of the Yiddish word "putz," what were you referring to -- what was your -- what was your -- referring to is your incredulity regarding Mr. Mister's statement, what was he referring to?
MR. SCOTT: Objection as to form.
THE WITNESS: I had a conversation with Steve Mister earlier in 2012. He actually called the agency to inquire about if we were taking action on DMAA. So I found it a little interesting that, you know, he was trying to get information out of the agency, which he didn't, and now seemed to be politicizing the agency's action, so to speak, in his comments, his quotes.
(Exhibit 16 was marked for identification.)

BY MR. WENIK:
Q Dr. Fabricant, I've placed before you a document that I've marked for identification as Fabricant Exhibit 16, which is a memorandum from a Louis Carlacci and Ying Lin to you, dated May 17, 2012, and it's a 12-page document, and I don't have a lot of detailed questions about it, but feel free to take a look at it.
My first question is: Is this something that you recall seeing?
A Yes.
Q All right. Who is Louis Carlacci?
A He was a reviewer on the NDI team, a chemist.
Q And who is Ying Lin?
A Ying Lin was originally an ORISE fellow, Oak Ridge Institute of Science, who was brought in as a chemist.
Q And they were both -- these are both FDA employees, I take it?
A Yes, in the division.
Q All right, and their expertise was in chemistry for both of them?
A Yes.

Q And they directed this memorandum to you and Corey Hilmas. Did you direct them to prepare this memorandum?

A Yes.

Q And what was the purpose of creating this memorandum?

A They did a further dive on some of the chromatography with regard to the Ping study. We had, again, had a meeting with Peter Hutt, who was USPlabs' counsel at the time, where he raised the Ping study a number of times.

And so while our initial, you know, our initial -- and this memo was after the first warning letter. We had an original read on Ping, but we dove further as it was ongoing, and we got more information. Ying also, given that she is a native Chinese speaker, was very helpful in that regard in translating the original text.

Q So if I understand your answer, do you believe that somebody had taken a look -- somebody within the FDA, rather, had taken a look at the Ping study before the April 24, 2012 warning letters went out, or did you look at the Ping study for the first time afterward as part of this

memorandum that we're looking at that's identified as Fabricant Exhibit 16?

A We looked at the Ping study long before this letter. This is just a deeper dive, and Ying made some very good corrections in terms of -- or found a lot of errors in a deeper dive on the Ping study.

Q Do you know how long it took them to prepare this analysis? Do you recall whether it was weeks or days or months?

A Weeks, I believe, but again I'd have to see the thread there to be sure.

(Exhibit 17 was marked for identification.)

BY MR. WENIK:

Q So, Dr. Fabricant, I've placed before you a document I've marked for identification as Fabricant Exhibit 17, which is a copy of a paper that was published in the Journal of Analytical Toxicology by a number of authors, including Mahmoud ElSohly and Ikhlas Khan, who we spoke about earlier.

My first question to you is: Have you seen this paper before?

A Yes.

Q Now, if you look at the top of the document, it says that it was initially published on June 25, 2012, which would have been after the date of the warning letter Fabricant filed that was April 24, 2012. Do you see that?

A Yes.

Q My next question then would be: Did you have access to the data underlying this paper or manuscript or draft of it prior to the warning letter that was issued on April 24, 2012?

MR. SCOTT: Object as to form.

THE WITNESS: When you say "data," do you mean were we knowledgeable that they were doing a study or final data?

BY MR. WENIK:

Q Let's take it in parts.

First, were you knowledgeable that the National Center for Natural Products Research was conducting this study?

A We were knowledgeable they were looking into DMAA, as well as were a number of people at the time.

Q All right, and my second question then

would be: Did you have access to some of their preliminary findings or data prior to the issuance of this warning letter that we've marked as Fabricant Exhibit 5?

A No, not that I recall.

Q All right.

Now, this article talks about Pelargonium oil and methyl hexaneamine or MHA. Would you agree with me that methyl hexaneamine or MHA is just a synonym for DMAA?

A It is.

Q And if we look at the very last page of the document, there's an acknowledgements section. It says that "this project was supported in part by the U.S. Anti-Doping Agency in Colorado Springs."

Do you see that?

A Yes.

Q Were you aware that the anti-doping agency was providing some funding for this work?

MR. SCOTT: Objection. Time frame.

THE WITNESS: Yeah.

BY MR. WENIK:

Q There's a fair objection.

Were you aware around, in the spring of 2012, that the anti-doping agency was providing some funding for this research?

A Honestly, I couldn't remember when exactly we knew that. You know, it didn't make a difference in terms of the warning letter. I mean --

Q Would it be fair to say that the lion's share of the funding would have come through the FDA via support from the National Center for Natural Products Research?

A I wouldn't say that's correct, no.

Q Would the FDA have provided some of the funding for this project?

A Again, I, I'm -- not having what was budgeted and those sorts of things, the line-by-line items, I'm not going to speculate to that. Obviously, the agency provided a lot of funding to the university over the years. To the extent that equipment was used, facilities were used that was supported by agency funding, okay, but no.

Q I'm going to talk a little bit more about Dr. ElSohly. Do you know if he has any

training in toxicology?

A I think you may want to -- well --

MR. SCOTT: Object as to form. If you know, you know, but don't speculate.

BY MR. WENIK:

Q No, I don't want you to speculate. If you don't know --

A I don't want to speculate.

Q Do you know whether he had any training in epidemiology?

A I'm not going to speculate.

Q How about pharmacology?

A He was a professor of pharmacology.

Q All right. Let's take Dr. Khan. Do you know whether he has any training in epidemiology?

A I don't.

Q Toxicology?

A He's published quite a bit of toxicological research.

Q Epidemiology?

A You asked that already.

Q For Khan? I don't think I asked that for Khan.

A Yeah.

Q Refresh my recollection. Did you say you didn't know?

A I didn't know.

Q Okay, but would you agree with me that their primary expertise is chemistry?

MR. SCOTT: Symptom.

THE WITNESS: Again, natural products chemistry is largely what they're known for, but it's a multidisciplinary science.

BY MR. WENIK:

Q Do you know whether Dr. Khan has any legal training?

MR. SCOTT: Object as to form.

THE WITNESS: I don't know.

BY MR. WENIK:

Q How about Dr. ElSohly?

A I don't know.

MR. SCOTT: Same objection.

BY MR. WENIK:

Q All right. Take a look at page 12 of the article, and let me ask this foundational question before I ask you the question about page 12.

Did you provide any feedback or review of drafts of this article before it became published, "you" meaning you personally, not the FDA?

A I don't believe so.

Q Do you know whether anyone else in the FDA provided any editing or comments to drafts of this article before it was published?

A Not that I know of.

Q All right.

Looking at page 12, and on the column to the right, there's a paragraph that begins "a dietary supplement, according to DSHEA, is a product that is labeled as a dietary supplement and is not represented for use as a food or as a cure for any disease," and then there's a discussion about DSHEA and NDI that goes to the bottom of that page and a little bit over to the next page.

Do you see that?

A Yes.

Q All right. When you read this document, when you saw this study, did you find it somewhat odd that chemists were commenting on DSHEA and its

interpretation?

A It happens frequently in the dietary supplement arena. People mention regulatory status frequently, whether or not it's correct, but it is mentioned frequently.

Q Do you consider either of these gentleman, Khan or ElSohly, regulatory experts?

MR. SCOTT: Object as to form.

THE WITNESS: I mean they're very good chemists. Regulatory experts? Again, they've never worked at the agency, so I wouldn't -- I think they have some general knowledge. They help training inspectors, they do things that are available, so in some vein, yeah, they are regulatory experts. University of Mississippi still helps to train FDA inspectors.

So they are very familiar with the agency. We certainly provided training to them over the years when I was at the agency, so I think they're knowledgeable.

BY MR. WENIK:

Q Take a look at the next page, page 13. I'm looking at the right-hand column, and it says,

"There is reasonable cause for concern regarding the safety of MHA, given two published case reports in which ingestion of MHA resulted in severe adverse events, including cerebral hemorrhage."

Do you see that?

A Yes.

Q All right.

Are either of these gentlemen, Khan or ElSohly, clinicians, to your knowledge?

MR. SCOTT: Object as to form.

THE WITNESS: They're not clinicians. I didn't know you needed to be to cite a study.

BY MR. WENIK:

Q Do you consider them experts on the safety of natural products?

MR. SCOTT: Same objection.

THE WITNESS: They're not -- that's not their area of expertise. However, they certainly can cite things that are in the literature as scientists.

MR. WENIK: Do you consider them qualified to evaluate a case report in the

same vein that you are?

MR. SCOTT: Same objection. Object as to form.

THE WITNESS: Again, this is for the purpose of publication. My evaluation of this was for the purpose of upholding the law, so it's a different, different area. I think, you know, what they're writing is all based on what's in the literature.

BY MR. WENIK:

Q Did you think it was odd that chemists who were publishing a study with chromatograms and analyzing whether something is in a plant or not are commenting about the safety of DMAA?

A Well, again, it's more than just chemists here, but on the publication list, no. Again, it's not uncommon, and they're citing the literature. It would be uncommon if they didn't cite the literature.

(Exhibit 18 was marked for identification.)

BY MR. WENIK:

Q So, Doctor, I placed before you a document marked for identification as Fabricant

Exhibit 18.

The top of the document appears to be an email between Mahmoud ElSohly and Ikhlas Khan. The bottom seems to be the press release that was in email form that we have in Exhibit 14.

Do you see that?

A No, they're not the same documents, but that's fine, because obviously this and this are different, how they're formatted, the text.

Q That was going to be my next question. Did you forward to them some version of the press release? And you are correct; it is formatted a little differently. That was going to be my next question.

A It's computer formatted differently. This we sent around so people were aware of it.

Q Okay. Did he call you to congratulate you on the issuance of the warning letters and the press release? Did Dr. ElSohly call you?

A I don't think he did, but I heard from Khan.

Q And what did Khan tell you?

A I think he was, you know -- he was happy, he was supportive, but . . .

Q Did both of these gentlemen express to you their personal view -- well, let's take them one at a time. I don't want it to be a compound question.

Did ElSohly express to you -- you personally, not the FDA as a whole -- express to you his belief that he thought DMAA was dangerous?

MR. SCOTT: Object as to form.

Time frame.

BY MR. WENIK:

Q At any time.

A Again, people had a lot of different opinions on it. Dr. ElSohly's opinion and Dr. Khan's opinion were largely very informative on the presence of DMAA in geranium. So what people may have thought otherwise? Okay, people have opinions. We still have a process, and it's still -- the agency has to be accountable, so I guess I don't know the relevance of anyone's opinion other than the work the agency put into work the process and be effective regulators.

Q Putting your view as to relevance aside, did Dr. ElSohly express to you ever his personal belief that he thought DMAA was dangerous?

MR. SCOTT: Object as to form.

THE WITNESS: Again, I'm not going to speculate. I'm sure he did. I heard a lot of different things on DMAA from a lot of different people.

BY MR. WENIK:

Q Did Dr. Khan express to you at any time his personal belief that DMAA was dangerous?

MR. SCOTT: Same objection.

THE WITNESS: Same answer. They might have. Again, it's not really relevant.

BY MR. WENIK:

Q Okay. Did Dr. Khan express to you his belief that DMAA should be removed from the marketplace?

A It's not relevant. That's not his decision to make.

Q I understand that. However, did he express that belief to you?

A Again, a lot of -- people said a lot of different things on DMAA. As to specific conversations, I, I mean there's nothing I can really say. Just speculate. I can't remember every conversation I had on every action we've

ever taken.

Q Do you recall whether Dr. ElSohly expressed to you at any time that his belief that DMAA should be removed from the marketplace?

A Again, I -- their opinion was valuable in the presence of DMAA in a plant. That's what I remember speaking with them about.

Q So would it be fair to say that Dr. Khan's opinion expressed to you was that DMAA was not in geraniums?

A The opinion and the science. I mean if there's a time you want to talk about it, yeah, because obviously they did a study, and that's going to shape his opinion on whether or not it's in there.

Q Did he express to you that opinion in 2012 after he prepared this study that we've marked as Exhibit 17?

A I think looking at the literature, it was long before 2012 that we started to discuss whether or not it was present.

Q And his view was that it was not?

A Well, again, looking at the science, yeah, his view was that, you know, looking at the

science, it was very, very odd, as someone who has a natural products background as well, you generally won't have a plant that's that well studied that all of a sudden there's a new compound that no one has seen before, and that it's there in exactly equal parts four times over, so yeah, I think those things struck him as odd, but you'll have to ask him about that.

Q How about Dr. ElSohly; did he express to you the view around the time of before the publication of Fabricant Exhibit 17 that he didn't believe DMAA was in geraniums?

A Before we discussed it, University of Mississippi was the center of excellence for the agency, so on ideas relating to botanicals and botanicals being the subject of regulatory action, I made use of the center of excellence and consulted their opinions on some things in addition to the FDA internal opinions.

Q And was Dr. ElSohly's opinion like Dr. Khan's you've described, even before publishing this study, that DMAA was not in geraniums?

A Again, his opinion -- and you need to

ask him -- was based on what he had seen in the literature and so forth and the oddities there, that it raised more questions than it answered.

Q And was his belief that it was unlikely that DMAA was in geraniums?

A I'm not going to speculate to his belief.

Q Well, what did he say to you?

A Well, what he said to me was based on what we had seen in the science. There were a lot more questions than there were answers.

Q And was his view expressed to you that the science pointed to DMAA not being in geraniums?

A I think that that was his view, yes.

MR. WENIK: Why don't we take a break for lunch?

MR. SCOTT: Sure.

(Whereupon, the lunch recess was taken.)

(Exhibit 19 was marked for identification.)

BY MR. WENIK:

Q Doctor, I placed before you a document

that I've marked for identification as Fabricant Exhibit 19, which is -- there's an email from Dr. Khan to you at the top of April 30th, forwarding an AHPA update.

Do you see that?

A Yes.

Q Have you seen this document before?

A Yes.

Q What is the AHPA?

A American Herbal Products Association.

Q And what relationship, if any, does that entity have with the NPA?

A Just another trade association.

Q And if we note the date, it's April 30, which is shortly after the press release we had identified as Fabricant Exhibit 13, and so the press release I take it generated some news coverage in various period publications; is that right?

A Yes. Anytime the agency does anything, it's a public agency.

Q Okay, and did this spark any conversation between you and Dr. Khan regarding the action that was taken against these various

companies?

A I mean I think he was happy. A lot of people were happy, because it -- you know, again, the burden -- what people see externally at the agency is one thing. The work that goes into making a case and things like that is quite another. So I think Dr. Khan was happy that the agency had taken action. You know, I think there was a lot of people that shared that sentiment, that there's -- it was odd that DMAA was even supposed to be there.

Q All right.

(Exhibit 20 was marked for identification.)

BY MR. WENIK:

Q So I have another email chain or rather extension of the email chain that began here in Fabricant Exhibit 19 with a couple more emails in Fabricant Exhibit 20.

I guess my first question is: Are you in the email chain that we have identified here in Fabricant Exhibit 20? Does your name appear?

A Yes.

Q And it's an exchange between you and

Dr. Khan where you said, "As Norm used to say', Never underestimate the predictability of stupidity.'"

Who is Norm? Who are you referring to?

A My Ph.D. advisor, but he is no longer with us. Norm Farnsworth.

Q And you wrote, "It's amazing that folks can still say it's in the plant."

By "in the plant," were you referring to geranium?

A Yes. I think, you know, it was from a -- we were excited at the agency about protecting public health. You had something here that was put forth that it was very, it was very concerning.

Q All right. Take a look at the second page of this document if you don't mind, Fabricant Exhibit 20.

A Sure.

Q So there's this blurb again from the AHPA, and look at the third full paragraph, the last sentence. "In AHPA's views, if DMAA exists in geranium through the plant's own synthesis processes, human-synthesized DMAA is also a lawful

dietary ingredient."

Is that a proposition that you disagree with?

MR. SCOTT: Object as to form.

THE WITNESS: I'm sorry. Would you point out where --

BY MR. WENIK:

Q I'm looking at the third full paragraph, the very last sentence. It says, "In AHPA's view, if DMAA exists in geranium through the plant's own synthesis processes, human-synthesized DMAA is also a lawful dietary ingredient."

My question is whether you disagree with that, that proposition.

A Well, there's two propositions in that statement. Which one are you asking if I disagree with; if DMAA is in the plant or if human-synthesized DMAA is also a lawful ingredient?

Q Well, let's take the last one. Is human-synthesized DMAA a lawful dietary ingredient?

A That would not be the agency's position, no.

Q Okay, and I take it even if it existed in the plant, that would be your position?

A Well, again, I think that when you're dealing with synthesis of a botanical, there are certain factors that need to be considered, so I don't think that this accurately -- this statement accurately captures that.

Q What other things need to be considered, in your opinion?

A Well, the agency just released a new guidance, draft guidance on NDIs where they talk about chirality and they talk about things like that. So just because it's synthesized wouldn't make it lawful. Other things would have to be considered appropriately.

(Exhibit 21 was marked for identification.)

BY MR. WENIK:

Q Dr. Fabricant, I've placed before you a document that I've marked for identification as Fabricant Exhibit 21, and let me put an explanation on the record.

The first page has a Bates number of GOV-007039. The document that's attached to it

has a different Bates numbering system. I'll represent to you that the government did not produce the attachments to emails to us sequentially documented, but we were able to determine from the metadata and the families which went with which.

So I'll represent to you that it's my belief that the document that begins GOV-012486 is the attachment that's identified in the document that belongs to Fabricant Exhibit 21.

A Okay.

Q At any rate, we talked before, I think, about -- I think you mentioned in passing Frank Jaksch, and he is a founder of ChromaDex; is that right?

A That's correct.

Q All right, and he sent you -- do you recall him sending you, back in August of 2012, the Li study that purported to find DMAA in geranium?

A Do I remember it, no, but obviously it happened. It's right here, and I'm pretty sure we had it before he sent it to us.

Q Okay, and do you recall whether you

reviewed this study at the time it came in to the FDA sometime in 2012?

A When it came in, yeah, of course, we reviewed it.

Q Okay, and what reaction did you have when you saw the study, the best you can recall? I understand we're talking four years later. What was, best you recall, your initial reaction to it when you first saw that study?

MR. SCOTT: Let me stop and impose an objection.

You can answer the question to the extent that it relates to any positions that you have taken public or the agency has taken public, but if there are conversations, analysis that went on before there being a public position regarding the study and how it goes into your analysis, you should not reveal those, because those are part of the deliberative process privilege.

THE WITNESS: Yeah, I think we -- there's really nothing to say.

BY MR. WENIK:

Q Does this spark a conversation that you

had with Dr. Khan after you saw this paper?
A Yes.
Q Let me show you this.
(Exhibit 22 was marked for identification.)
BY MR. WENIK:
Q So I've just placed before you Fabricant Exhibit 22, which is an August 8th email from Dr. Khan to you, which simply states, "I'm sure you saw the DMAA paper. I think you should get fresh material which they received from China and analyze to find all isomers."
So I'm looking at the other document, Fabricant Exhibit 21, which is also dated August 8, so let me just, now that I've placed this in front of you, first of all, does Fabricant Exhibit 22 have your name in the email chain?
A Yes.
Q And looking at this, does this refer to the Li paper that was seen in Fabricant Exhibit 21, the other DMAA paper?
MR. SCOTT: Exhibit 22.
BY MR. WENIK:
Q Right.

A I believe it does.
Q All right, and --
A I didn't write the email, so . . .
Q Right. What is your recollection of what conversation was sparked when Dr. Khan emailed you about this paper, saying that you should get fresh material?
A Well, I think when we saw the paper, we knew what our burden would be at the agency in terms of, in terms of moving ahead.
Q And what was that burden?
A Well, I think that, you know, we had -- USP continued to provide some science. We certainly felt very good about our scientific base, but we anticipated that there may possibly be a question about, okay, what about this study, and so we repeat it. Generally that's what you do if you get an outlier result. You find a way to substantiate it.
So this was an outlier result, and so you don't just publish this and go "okay, that's it, it's done" for something that's never been seen before in a plant that was extensively studied for -- I mean the economic impact of rose

geranium oil, 50, 75 years, it was extensively studied. The plant had been effectively ripped apart by phytochemists and every component isolated, so when people show up and go, "oh, yeah, we found it, hey, accept it," that's generally not how it works. You generally need confirmation, and so that was the discussion.
Q And did you discuss with Dr. Khan about having the center down in University of Mississippi do a follow-up study?
A Yes.
Q Having read the Li paper at the time, did that raise a question in your mind whether geraniums might actually have DMAA in them?
A I -- you know, I only comment on this paper and the memo and some of the challenges with it, so I'll stand on that.
Q All right.
(Exhibit 23 was marked for identification.)
(Exhibit 24 was marked for identification.)
BY MR. WENIK:
Q Have you had a moment to look at what

I've marked as Fabricant Exhibit 23 and Fabricant Exhibit 24, Doctor?
A Yes.
Q All right. Looking at Fabricant Exhibit 23 first, is your name in the email chain at the top from Ikhlas Khan to you?
A Yes. That's the only place it is.
Q All right. It looks like Dr. Khan forwarded to you an email he had received -- I'm sure I'll pronounce this wrong -- from Zhangwei-dong.
Do you know who Zhangwei-dong is?
A Yeah, they're part of Khan's network in China. They help get, they help get plant material.
Q Okay, and Zhangwei-dong had outlined to Dr. Khan -- it says, "Dear Ik, I got your problem in MHA analysis of natural-derived samples. I agree with you that it's an essential and important question to make sure whether natural materials contain detectable qualities of MHA, and I'm glad to help you as much as we can in the first time. We could do the work as following," and then he talks about collecting samples.

Do you see that?
A Yes.
Q All right, and Dr. Khan asked, "What do you think about this strategy?"
A Yes.
Q And was this email exchange part of what you just referred to before, that in the wake of the Li paper, you were talking about doing another study with the University of Mississippi; is that right?
A Yes.
Q Okay, and we have this other email here, Fabricant Exhibit 24, an August 9, 2012 email from you to Dr. Khan.
Do you see that?
A Yes.
Q Okay, and you said "I like it." Is that "I like it" responding to the strategy that's outlined below in the other emails?
A Yes.
Q And you wrote, "The other issue is look at that waters system, it's older than waters." What is that referring to, looking at the waters system?

A It's the HPLC system.
Q So that means you were concerned about the testing methodology that was used in the Li paper?
A Yes.
Q Okay, and then you wrote, "Plus I don't think that LOD is real."
Does "LOD" stand for "level of detection"?
A Limit of detection.
Q Okay, and were you saying that you didn't think that the limit of detection was real in the Li paper? Is that what you were referring to?
A Consulting with my chemists, they raised a flag on that, that it seemed very odd, the concentrations that were there, the ranges.
Q All right, and was there, in the wake of these communications, a multi-centre study of geraniums that was, for lack of a better word, "quarterbacked" by Dr. ElSohly and Dr. Khan at the University of Mississippi?
A Well, they -- I mean they were getting plant material. Multi-centre, I don't --

Q Well, let me show you the argument. It's not a memory quiz.
(Exhibit 25 was marked for identification.)
BY MR. WENIK:
Q I've marked for identification Fabricant Exhibit 25, which is an article offered by Dr. ElSohly, Dr. Khan, and others that came out in August of 2014, I think right after you left the FDA. And if you look at the abstract, it talks about them using -- I call it multi-centre. They talk about using four different sites for analysis of geranium samples, I suppose.
Does this -- Fabricant Exhibit 25, is this publication a culmination of the new testing and research that we were talking about early on that eventually took place?
A Well, I mean if this was -- this is an extension of this work and getting those samples and evaluating, reevaluating it.
Q So the samples we're talking about in Fabricant Exhibit 24 and Fabricant Exhibit 25, that strategy ultimately culminated in the study we have as Fabricant Exhibit 25?

A That would be what I would think. Obviously, there were other samples, too.
Q Right. I understand.
So let me show you another couple of documents.
(Exhibit 26 was marked for identification.)
(Exhibit 27 was marked for identification.)
BY MR. WENIK:
Q So, Doctor, I've placed before you what I've marked for identification as Fabricant Exhibit 26, which is an email chain between you and Vincent Bunning and some others, and which -- looks like it encloses an article, a news account.
A Mm-hmm.
Q Is that right?
A Yes.
Q All right, and your name is in the email chain?
A Yes.
Q And I take it you've seen this before, this email chain?
A I have.

Q And then I marked as Fabricant Exhibit 27 a study by Fleming, talking about an analysis and confirmation of DMAA.

Do you see that?

A Yes.

Q All right. So turning to Fabricant Exhibit 26, the article that's in the email by Stephen Daniells, dated December 3, 2012, talking about the study -- he talks about a study published in Analytical Chemistry Insights.

Is that -- is he referring -- is it your understanding, looking at this, that he's referring to what I've marked as Fabricant Exhibit 27?

A Yes.

Q All right, and do you believe that you had seen the study that I've marked as Fabricant Exhibit 27 back in December of 2012 around when it first came out?

A Mm-hmm, yes.

Q Okay, and you have some email exchange here between some individuals. I'd like to first go through who they are.

Who is Vincent Bunning?

A He was the deputy director for the Office of Regulatory Science.

Q All right. I think you mentioned Steven Musser earlier. Was he a --

A At that point he was just the office director.

Q And then we've already talked about Mr. Hilmas.

So then we have Jeanne Rader. Who is that person?

A She was the division director in that office.

Q And the article talks about some findings made in Fabricant Exhibit 27, and you wrote an email to these individuals saying "pretty ridiculous."

What was your, the basis for your thinking that the findings were "pretty" -- well, let me step back.

When you said something was "pretty ridiculous," did you think the findings in the study were pretty ridiculous or the fact that the study had been done?

MR. SCOTT: Object as to form.

THE WITNESS: This is all covered in the memo. There are a lot of questions with this study and the supposition that -- it was seemingly only found from the company's research, that all these other experts in botanicals couldn't find it, but yet it just kept showing up again and again and again. There was no biosynthetic pathway. There was nothing that made it clear that it was even possible; yet it just kept showing up in the company's research which wasn't even peer-reviewed.

So yeah, I think in terms of protecting the public health, it seemed kind of ridiculous.

BY MR. WENIK:

Q And so for "the company," I think you're referring to USPlabs, is that correct, that they were the ones that sponsored these studies?

A Yes.

Q All right, and you don't believe that this journal Analytical Chemistry Insights is a peer-reviewed journal?

A It's not. It's an open-access journal.

Q So I take it you had some questions about the validity of this research that's reflected in Fabricant Exhibit 27?

A I think that's clear in our letter back to USPlabs.

Q Let me ask you this. You mentioned that, the concern about it, having seen it in studies sponsored by USPlabs. Would your view -- would you have had less questions if the research had been done by an objective, neutral third party?

A I can't say. It's speculation. What I can say is when you -- and as we pointed out, you have these questions that remain unanswered, and they were only showing up, again, positively in the company's research in non-peer-reviewed journals. It wouldn't be hard for the company to approach a botanical expert and say "what do I need to do to substantiate this finding." That would be what a responsible company would do. At no point in time was that made evident.

Q Let me ask you this: So in your conversations with Drs. Khan and ElSohly leading up to the research that culminated in Fabricant

Exhibit 25, did you give them any goal that you wanted them to achieve, such as disproving that DMAA was in geraniums?

A I didn't think it was there, but the science is going to be the science. I wanted them to do the science. The science will ultimately tell the tale. I knew they did good science.

Q So you didn't -- would it be fair to say you didn't give them marching orders about what findings you wanted them to come up with or anything like that?

A No. I wanted the science done.

(Exhibit 28 was marked for identification.)

BY MR. WENIK:

Q Doctor, I've placed before you a document I've marked as Fabricant Exhibit 28, which for the record is a download of a posting on the FDA's website, and it's entitled "Stimulant Potentially Dangerous to Health, FDA Warns."

If you'd take a moment to look at this, my first question to you is whether you recognize this warning, this warning document.

A Yes, I do. It's a consumer update.

Q All right, and did you draft this consumer update?

A I worked with the Office of Public Affairs to draft it, yes. I wasn't the only one.

Q All right, and whose decision was it to post it on the FDA website?

A The commissioner of the Office of Foods, Mike Taylor.

Q Did you agree with the posting of this on the FDA's website?

A I did.

Q All right. So I'm looking at the first page, and it says that "the Food & Drug Administration is using all available tools at its disposal to ensure that dietary supplements containing a stimulant called dimethylamylamine (DMAA) are no longer distributed and available for sale to consumers in the marketplace."

Do you see that?

A Yes.

Q Would it be fair to say that the goal of the FDA, at least at the point in time when this was drafted, was to remove DMAA from the marketplace?

A I think the goal was to protect consumers and public health.

Q All right, and part of doing that would be to remove DMAA from the marketplace?

A Part of that, yes.

Q Okay, and if you look at the second paragraph down, it says, "As of April 11, 2013, FDA had received 86 reports" --

MR. SCOTT: You said the second paragraph?

MR. WENIK: I'm sorry. You're right. Third paragraph.

BY MR. WENIK:

Q "As of April 11, 2013, FDA had received 86 reports of illnesses and deaths associated with the supplement containing DMAA."

Do you see that?

A Yes.

Q Now, turn to the second page of the document.

A Well, before you do that, the whole thing is in context there with regard to the report. You can't just take that sentence out of context. I think, you know, with adverse event

reports, it's important that all of that information is there.

Q All right. I was just candidly asking you about just do you accept the date of when this was created, because it says here that -- obviously, this was created at least on April 11, 2013, and then the next page I'm looking --

A Well, it wasn't created on April 11. That was the last time that, before this went out, that someone had checked. That was the last date you could verify the adverse event reports.

Q Right, but I'm saying that the posting and finalization of this document -- so I'm looking there. So you said you had some data as of April 11, 2013, and I'm looking at the next page, the first column, the first full paragraph.

You're talking about, in this update, "However, after reviewing the studies provided by USPlabs, FDA has found the information insufficient to defend the use of DMAA as an ingredient in dietary supplements. FDA is finalizing a formal response to the firm to reflect its findings, according to Daniel Fabricant, Ph.D.," and the final -- the formal

response, I assume, was Fabricant Exhibit 6, correct?

A Yes.

Q All right. So would you agree with me that means that this document must have been posted and created sometime, or finalized I guess is the better way to say it, sometime between April 11 and April 18 when this was finalized?

A Again, without the date there -- I'm not going to pretend to remember what happened between April 11 and April 18, to the exact, you know . . .

Q All right, and you wrote here in the second column on the second page --

A I wasn't the only author here.

Q No, but this actually quotes you. It says, "Consumers" -- I'm looking at the third full paragraph. "'Consumers may mistakenly looking at a capsule and think that FDA has signed off on that product as safe and effective prior to that product appearing on the market, as we do with drugs and other medical products,' says Fabricant. 'In contrast, with dietary supplements, there is no premarket approval, and once a product is on

the market, the burden is on the FDA to prove that the product is unsafe.'"

Do you see that?

A Yes.

Q All right, and do you believe that to be true?

MR. SCOTT: Object as to form.

THE WITNESS: For products that are legitimately dietary supplements, yes.

BY MR. WENIK:

Q Okay.

A Again, that product has to be lawful. It probably should say "with lawful dietary supplements, there is no premarket approval." That's important.

Q Okay. My question is -- so this document was posted, and I understand you don't want to be boxed into an exact date, and that's fair, but it's clear that you refer to that the formal response had not been finalized yet to the USPlabs submission.

So my question simply is: What was the reasoning to have this posted on the FDA website before that response was finalized? What was the

sense of urgency?

A I don't know that that's the case, and you don't know if that's the case either. It might have been this was written probably leading up to this, but in terms of a posting date, unless you have a posting date, I'm really not going to answer that question.

Q Well, if it was posted after that letter, then this would be inaccurate, right, in the sense that you're finalizing a formal response?

A It could have been posted after. Again, the timeline here is . . .

Q All right. Do you do consumer updates for all of FDA's case?

A For a lot of them.

Q Was there any particular reason why this one was selected to have a consumer update?

A It's a public health agency. This was something that was out there in the public health that was a large selling product that a lot of people used.

Q Do you know who designed the graphic on the first page with the words "Heart Attack" in

bold?

A The Office of Public Affairs.

(Exhibit 29 was marked for identification.)

BY MR. WENIK:

Q Dr. Fabricant, I placed before you an email with an attached article from a Brian Somers to you, dated March 17, 2013.

My first question is: Do you recognize having seen this before?

A Let me go through it.

Q Sure, please.

(Witness peruses document.)

THE WITNESS: Okay.

BY MR. WENIK:

Q Have you seen this before, what we've marked as Fabricant Exhibit 29?

A I believe I have.

Q All right. Who is Brian Somers?

A He worked for the Office of Nutrition, Labeling, and Dietary Supplements.

Q So he was one of your subordinates when you were at the FDA?

A He eventually became one, but not during

this time period.
Q All right.
A He was in another, another part of the office.
Q All right. Do you recall being interviewed for an article by the New York Times about DMAA?
A I was interviewed a lot of times by the New York Times for a variety of things. DMAA was one of the topics.
Q My question is: Having looked at this article, this New York Times article that we've marked here as Fabricant Exhibit 29, do you recall whether that article was one of the reasons that the agency put out Exhibit 28, that consumer update, having seen this article?
A Again, that was the Office of Public Affairs and the Commissioner for Foods that were in charge of putting these out, so I supported putting that out. As to their decision-making and what role this had, you'd have to ask them that.
Q Okay. Fair enough.
Were you involved at all in a consulting capacity in anything in the litigation that

Michael Sparling, the soldier who is the subject of this article, brought against USPlabs?
A No.
Q Had you been following at all the results of that litigation?
A No.
(Exhibit 30 was marked for identification.)
BY MR. WENIK:
Q Doctor, I've placed before you a document I marked for identification as Fabricant Exhibit 30, which is a February 9, 2013 memorandum authored by you, and please take a moment to look at that. My first question is whether you recognize the document.
(Witness peruses document.)
THE WITNESS: Yes.
BY MR. WENIK:
Q So looking at this document, you referred before that some memoranda may have been prepared prior to Fabricant Exhibit 6 going out.
Is this document, Fabricant Exhibit 30, a memo that you shared with Jennifer Thomas for her to use in helping to craft Fabricant Exhibit

6?
A Yes. In the "to" line, it's to the Division of Enforcement. There I believe were other documents as well.
Q And would it be fair to say that the analysis that Ms. Thomas set forth in this letter that you agree with that analysis in Fabricant Exhibit 6?
A Yes. I mean we continued to work together on the letter as it was being developed.
MR. SCOTT: Let's take a break for a minute.
MR. WENIK: Sure.
(Whereupon, a short recess was taken.)
(Exhibit 31 was marked for identification.)
BY MR. WENIK:
Q Doctor, I've placed before you a document that I've marked for identification as Fabricant Exhibit 31, which for the record is a printout from the US Food and Drug Administration website, dated July 16, 2013, and it's a Q&A about DMAA.

A Mm-hmm.
Q So my question to you is: Have you seen this before, this Q&A about DMAA?
A Yes.
Q Did you draft this Q&A, or --
A I worked with our Office of Public Affairs and the attorneys.
Q All right, and the questions and answers, you feel that they're accurate?
Let me rephrase that. You feel the information provided in the answers to the questions are accurate?
A Yes. I mean, you know, so long as it's taken in the proper context, yeah, everything is right on.
Q All right. In the first sentence where it says "What is DMAA," it says, "DMAA is an amphetamine derivative."
What was the basis to your understanding -- factual basis for asserting that DMAA is an amphetamine derivative?
A Well, that was language that they wanted to use to warn people. Again, we do know it behaves like an amphetamine, so I think that that

was thinking on that one.
Q Did Dr. Cohen, Pieter Cohen suggest using that language to you?
A No.
Q And I'm looking at a block here that says "How does FDA regulate ingredients in dietary supplements like DMAA," and in the fourth line from the bottom, it says, "However, in order for FDA to ban a compound in a dietary supplement, FDA is required under the statute to undertake a series of lengthy scientific and legal steps."
What's your understanding of what this series of lengthy scientific and legal steps are that are required to ban a dietary supplement?
A Dietary ingredient. They would be the same that were taken in ephedra, but that supposes first that it's an actual dietary ingredient. With DMAA, that wasn't the case, wasn't the ultimate rendering.
Q Okay.
A That is important. You can't ban something that's not a dietary ingredient.
(Exhibit 32 was marked for identification.)

BY MR. WENIK:
Q Dr. Fabricant, I've placed before you a document I marked for identification as Fabricant Exhibit 32, which is an email between you and Ikhlas Khan and Troy Smillie.
A Smillie.
Q Have you seen this before?
A Yes.
Q Who is Troy Smillie?
A He used to work with Ikhlas Khan at University of Mississippi.
Q Is he a scientist of some sort?
A He is a Ph.D.
Q Is his area of expertise chemistry as well?
A His degree is in pharmacognosy.
Q All right, and I notice here there are some links to stories about DMAA that you emailed to Dr. Khan; is that right?
A Yes, as they had to -- you know, they have to report on their activities, and so we had some conversations about that they had the new stories that were out there on it in terms of, you know, what the, quote-unquote, "interaction"

between them and the agency was and what some of the hot topics were, if you will, so I was just sending him some articles that were out there.
Q Okay. Was he providing you updates about, as we discussed earlier, oh, maybe a half hour ago, that they were going to do some more research on DMAA and geraniums? Were they giving you updates on the progress of that research that they were doing?
A We talked about it. We talked that it was ongoing.
(Exhibit 33 was marked for identification.)
BY MR. WENIK:
Q Doctor, I've placed before you a document that I marked for identification as Fabricant Exhibit 33, which is a copy of an article from the Atlanta Journal-Constitution from November 2, 2013. If you could take a couple of minutes to read through the article, I want to ask you a couple questions about this.
(Witness peruses document.)
THE WITNESS: Okay.

BY MR. WENIK:
Q All right. So having looked at this article that I placed before you as Fabricant Exhibit 33, does this refresh any recollection you might have of having been interviewed by Danny Robbins of the Atlanta Journal-Constitution a couple years back?
A I remember talking to Danny.
Q And on page 3 of the article it talks about this interview, and he wrote, Mr. Robbins wrote that "the FDA's top supplement official, Dan Fabricant, acknowledged that the FDA was familiar with Wheat but wasn't aware his companies were selling DMAA products until informed by the newspaper."
Is that accurate, that statement?
A I'm not entirely sure that it is.
Q Okay. After you had this interview with Mr. Robbins, did you direct an inspection to be taking place of the facilities of Hi-Tech Pharmaceuticals in Georgia?
A I believe we worked with -- there was another issue at the same time we were focused on, and it's right here in the ingredient, acacia

rigidula. It was another NDI we were concerned with, had gone unfiled and more than likely wasn't actually a dietary ingredient. So in working with the district office in Atlanta, we wanted to inspect the facility.

Q Was the impetus for the inspection the conversation that took place with this journalist?

A Again, I can't -- that wouldn't have been the reason. The reason would have been if he was out there selling DMAA, as the agency had already taken plenty of action on DMAA, it didn't matter who it was, that we were going to continue those efforts to -- you know, it is the agency's authority to take those products that are adulterated off the market.

So given that there were seizure actions already put forth, and one by that district, that district also handled the seizure that was in Anderson, South Carolina, the Atlanta district office. It was -- again, where we saw it, we, we took the appropriate steps to defend the public health per our legal authority.

Q Were you aware or -- let me rephrase it. So before that interview with the

Atlanta Journal-Constitution journalist, was the agency aware that Hi-Tech Pharmaceuticals was selling DMAA-containing products?

A It was -- again, if, if memory serves, I thought we already had inspectors in there, and the inspectors had pointed it out because we were looking at this other issue, but again, it doesn't really seem to be -- if it's there, we took appropriate action. It's not a lawful dietary ingredient.

Q What role, if any, did you have with the inspections that took place in 2013 at Hi-Tech Pharmaceuticals?

A It may have been a for-cause inspection, but I don't know if initially it was a for-cause inspection, but then it became a for-cause inspection when we realized there was DMAA at the facility.

Q And what is a for-cause inspection?

A That means that the inspectors, through the district, are directed to go out to a facility and really get a handle on what exactly is the nature of the issue.

Q Did you brief the inspectors that went

onto these inspections at Hi-Tech Pharmaceuticals?

A Didn't have to. They were already briefed from the GNC case.

Q Did you provide them additional information about Hi-Tech Pharmaceuticals or Mr. Wheat?

A Didn't have to. All the documents were pretty much prepared. They were the exact same documents we used in the GNC seizure, if memory serves.

(Exhibit 34 was marked for identification.)

BY MR. WENIK:

Q Dr. Fabricant, I've placed before you a document with Bates number GOV-003535 through GOV-003544. If you'll flip through that for a minute or two, I want to ask you a couple of questions.

A Okay.

Q Have you seen these documents before?

A Some of them yes, some of them no. These are -- these were between ORA, Office of Regulatory Affairs.

Q Did you know Robin Goins?

A I had spoken with Robin.

Q And I'm looking at the page GOV-003540. There's an email chain between Robin and some others at, I assume at FDA, and in the next to the last paragraph she talks about getting "samples analyzed as quickly as possible, as we are seeking serious regulatory action against this firm and are ready to get these products off the shelf."

Had you given instructions that this matter was to be expedited or given priority in some way, this matter against Hi-Tech?

A Well, I mean when there's a product there that the agency has already acted upon, you don't really need to tell anyone to step on it. They were -- you know, you don't see me on that thread. That looks like them telling them to expedite it, so that's their words. I mean you always want to take fast action if it's an adulterated product. That's kind of the charge of the agency.

Q Okay. Take a hook at the page that's marked on the bottom 003541.

A Okay.

Q And the next to the last paragraph talks

about: "Due to the urgency of this case and previous issues with this firm, how soon can we expect results and is it possible to have the results as soon as possible?"

Were you aware of previous issues with Hi-Tech Pharmaceuticals?

A The district certainly was, and as you can see, I'm not on this. This is from Robin Goins. I don't --

Q If you don't know, you don't know. If that's the answer, that's fine.

A We have a record of folks' activities, and . . .

Q Okay. All right. We're getting near the end.

(Exhibit 35 was marked for identification.)

BY MR. WENIK:

Q Okay. So I marked for identification as Fabricant Exhibit 35 an email chain that has some emails and some talking points, and my first question to you is: Do you recall seeing this document?

A Yes.

Q All right, and who is Tamara Ward?

A She worked in the Office of Media Affairs.

Q All right, and the talking points that are attached to this email chain, did she draft those or did she draft them in consultation with you?

A There were people at OPA, and they consulted. We went back and forth. I'm sure the attorneys looked at them.

Q All right, and were you satisfied with the adequacy of the talking points?

A It was, it was fine. I mean it wasn't, it wasn't perfect. I mean we already had done some press on it. I think the key thing or the key message is in there, and that's usually what we focused on in interviews.

Q Okay. I'm looking at the talking points, and it talks about the history of DMAA, and in the next to the last line, it talks about "it appears to have always had the same API in the same strength, 250 milligrams."

Do you see that?

A Mm-hmm, yes.

Q "API," does that stand for "active pharmaceutical ingredient"?

A It does.

Q And it talks in the email chain about an interview with NBC News and you to discuss the history and use of DMAA, and that interview took place; is that right? You eventually sat down with him?

A Yes.

(Exhibit 36 was marked for identification.)

BY MR. WENIK:

Q So, Doctor, I've placed before you an email chain that I don't think you're a part of, actually. I don't think I see your name here.

A No.

Q Well, you're spoken about in the third person, but more so I wanted to ask you some questions about identifying people.

So I guess I should ask you: Have you seen this before I just showed it to you? I assume not.

A No.

Q All right. Mark Blumenthal of the

American Botanical Council, do you know that gentleman?

A I do.

Q Who is Mark Blumenthal?

A He started the American Botanical Council.

Q Is this someone you had conversations or contact with while you were at the FDA?

A I've known Mark since I was in graduate school.

Q I take it the answer is yes?

A Yes.

Q Okay, and who is John Cardellina?

A John Cardellina, I've known him for a while, too. He's a natural products researcher.

Q Okay, and then we have a mark@herbalgram.org. Do you know who that is?

A That's Mark Blumenthal.

Q All right, and then we have a person listed here as James Neal-Kababick, Flora Research. I think we've already asked you about him.

How about Anthony Almada? Who is that? Do you know anything about him?

A Yes, I do. He's done research on natural products and dietary supplements.
Q It looks like his email is a place called "imaginutrition.com." Do you know what that is?
A Imagine Nutrition, one of his companies, yes.
Q Okay, and then we have a Stefan Gafner. Who is Stefan? Do you know Stefan Gafner?
A Yes.
Q Who is he?
A He was a -- he used to work at Tom's of Maine. He's a natural products chemist.
Q All right, and then there's someone here, Tyler Smith at herbalgram.org. Do you know who that is?
A He works for Mark Blumenthal.
Q All right. So Mark Blumenthal is writing to Mahmoud ElSohly, who we've talked about, talking about him, and the email is dated April 15, 2013. "I appreciate seeing your presentation this morning here at the Oxford ICSB on your newest multi-center research on DMAA and geranium leaf and oil."

Do you see that?
A Mm-hmm, yes.
(Exhibit 37 was marked for identification.)
BY MR. WENIK:
Q Doctor, I've placed before you as Fabricant Exhibit 37 the agenda that I pointed out from the archives page on the ICSB website back for a conference that took place in April of 2013 that's referred to as Fabricant Exhibit 36.
Do you see that?
A Yes.
Q And it lists you, back in 2013, that you were a session chair of one of the programs at this conference; is that correct?
A Yes.
Q And what is the ICSB?
A International Conference on the Science of Botanicals.
Q And what is your understanding of what that -- is that associated with the University of Mississippi and center?
A It has been for quite some time, yes.
Q All right, and I take it the conference

was held -- is this an annual conference?
A Yes.
Q And I take it this is held in Oxford, Mississippi, near the university or on the university campus?
A A little bit of both.
Q Okay, and so if we look at this agenda that I've marked as Fabricant Exhibit 37, you're listed as having been the session chair, and then there's a description of a session by Dr. Mahmoud ElSohly entitled "A Multicenter Study Showing the Absence of DMAA in Pelargonium."
Do you see that?
A Yes.
Q All right. Do you recall whether you attended that session that Dr. ElSohly gave?
A Yes.
Q And during that session, did Dr. ElSohly mention, to your recollection -- and I know it's three years later, but I would think you would remember this if it happened. Did he mention that he had found DMAA in geraniums at that session?
A I don't believe so, but again, like I said, they published the paper. He definitely

said that they didn't confirm the presence of it, which is more important from where I was sitting.
Q All right.
(Exhibit 38 was marked for identification.)
BY MR. WENIK:
Q So, Doctor, I placed before you a document that I marked for identification as Fabricant Exhibit 38, which I'll represent to you is the slide presentation that Dr. ElSohly gave at the ICSB conference in 2013.
A Okay.
Q And my first question to you is: What is your understanding as to whether or not a slide presentation like this -- what review, if any, does it undergo? Is it like a poster presentation where sometimes they peer-review these sort of things, or what is your understanding?
A No, it's -- I mean this was a, a rapid communication, if you will. It's not the same as the peer-reviewed process, but it doesn't mean it wasn't good work. It's just not the peer-review process.
Q And did Dr. ElSohly share with you these

slides before he presented them at the ICSB conference?

A No, but we got them after.

Q Do you mean the FDA got them after?

A Yes.

Q All right. So let me turn your attention to -- unfortunately, the pages are not numbered, but it's 11 pages from the end.

A 11 pages from the end?

Q I think you got it right there.

A Okay.

Q So we have a table there.

A Mm-hmm.

Q And one column lists various samples of Pelargonium.

A Yes.

Q Another column gives you a specimen number, and then the third column talks about DMAA, and then it says "ND."

Do you see that?

A Yes.

Q Would you agree with me the "ND" stands for "not detected"?

A I believe that's what it was in this

context, but interestingly enough, he doesn't have it notated, so I'll assume that's what it means.

Q All right. If we look back at the article that I showed you as Fabricant Exhibit 25, if you look at the third page in this article, there's a table, and similar to the page we looked at here, he has the specimen numbers in one column, and in the final column he has "ND," and he actually has a footnote here where he says "ND means no detectable levels of DMAA."

Do you see that?

A Yes.

Q And would you agree with me that both in the slides and in the article, the authors have listed that DMAA was not detected in any of the specimens that are listed here?

A That's what it appears to say.

(Exhibit 39 was marked for identification.)

BY MR. WENIK:

Q Doctor, I've placed before you a series of emails and attachments that I marked for identification as Fabricant Exhibit 39. I'll ask you to take a look at that for a little bit, and

then I'll ask you some questions.

(Witness peruses document.)

BY MR. WENIK:

Q I've placed before you Fabricant Exhibit 39. I understand that you didn't author these emails, but I want to ask you some questions anyway.

So on the first page there's a reference to using something called "the MRM method." What would your understanding be of what the MRM method stands for? As a chemist, what would your understanding be of what that stands for?

A In this instance, I'm not -- I didn't perform the analysis, so I don't know.

Q Okay. All right.

If we look back at Exhibit 25 and the table that we have on page -- Table 1 of the exhibit, which is at page 3. At the top of the table it talks about Table 1, and it says, "Pelargonium plant material and oil samples used in the study and the results of their analysis for DMAA," and then it goes on to talk about some of the different centers or laboratories that studied it, including the School of Pharmacy at Second

Military Medical University in Shanghai, China, and Shanghai Institute of Materia Medica.

A Yes.

Q Are you familiar with the Shanghai Institute of Materia Medica?

A Inasmuch that they are partners with the NCNPR. That's about the extent.

Q All right. Is it a nonprofit institution, a for-profit institution, or --

A As far as I understand, it's an institution of traditional medicine in China.

Q Okay, and I'm looking at Fabricant Exhibit 39. I'm looking at the Bates stamp page 2270 at the bottom.

A Okay.

Q And there's some chromatograms there, correct?

A Yes.

Q And then it says in Figure 5 -- this is entitled "Examination of DMAA in Pelargonium plant material, Shanghai Institute of Materia Medica," and then there are some chromatograms, and it says at the bottom, "MRM chromatograms of some plant samples. 1,3-dimethylamylamine was detected in S1

and S2. The isomer of 1,3-dimethylpentylamine was detected," and then it gives some sample numbers, 13040, 13041, 13047, 13048 and 13049.

Do you see that?

A Okay.

Q And if we look at the table in the chart for the corresponding sample numbers, the office wrote, contrary to what had been submitted to them by the Shanghai Materia Medica Institute, that DMAA was not detected, correct?

MR. SCOTT: Object as to form. It assumes facts clearly not in evidence.

You can answer if you can.

THE WITNESS: Yeah, I mean this isn't my -- you know, in reading this, I mean Khan's pretty clear about 2 nanograms is under the detection limit, it says right here, so there's -- I mean there's not confirmation, so that's what matters.

BY MR. WENIK:

Q Did Khan or ElSohly ever share with you these documents from the Shanghai Institute of Materia Medica?

A No, I don't have these documents, and I

wouldn't remember anyway. That was these years ago.

Q Do you know whether they shared that information with the FDA?

A Again, I -- this is --

MR. SCOTT: To the extent you know.

THE WITNESS: No, I don't know.

BY MR. WENIK:

Q Would you consider it an act of academic dishonesty to publish results for a center that were different than what had been communicated to you by the laboratory?

MR. SCOTT: Symptom.

THE WITNESS: Yeah, I don't know that that's the case, so I can't speculate.

BY MR. WENIK:

Q And I take it that at the ICSB conference in 2013 when we looked at the PowerPoints and similarly said none detected, there was no mention of any of these documents either, were there?

A You saw the same PowerPoints I did, so again this is -- you know, I don't know that what you're saying is a fact either. So if he's saying

2 nanograms is under detection limit, and in the email it says that it was under 2 milligrams, it sounds like it's below detection limit. So I don't know that what they presented was different from that.

Q If you look at --

A It's not a confirmation either way, and -- yeah.

Q If you look at the article, this one here, Fabricant Exhibit 25, so if you look at the fifth page.

A Okay.

Q There's tables 2, 3, 4 and 5.

A Yes.

Q And the authors of the study publishing the article, the limits of detection that were used by the Second Military Medical University of Shanghai china in these four tables; is that correct?

A Yes, but that's different than this.

Q Right. They don't include any information about the levels of detection used by the Shanghai Materia Medica, do they?

MR. SCOTT: Read as much as you

need to see if that's the case or not.

THE WITNESS: I don't see it here. However, is there a supplemental?

BY MR. WENIK:

Q Not that I'm aware of.

A "Additional supporting information will be found online version of these articles" --

THE REPORTER: Can you slow down, please?

THE WITNESS: Yeah. Do you have a supplemental?

BY MR. WENIK:

Q I do not.

If ElSohly and Khan had fabricated and manipulated the results of their study, would that change your view as to the regulatory action for the FDA to take in regard to DMAA?

MR. SCOTT: Object as to form.

THE WITNESS: They didn't.

BY MR. WENIK:

Q How do you know they didn't?

A Here is what I do know is you have it occurring in company-founded studies, company-paid-for studies in non-peer-reviewed

journals that no one else has ever replicated and the type of work that would need to be done to show, one, that it's possible for the plant. I'm not aware of a biosynthetic pathway that does it. Furthermore, I'm not familiar with a biosynthetic pathway in nature that produces exactly four optical isomers in identical quantities again and again and again.

There's I think ample findings, and the work of the government wasn't just dependent on the work Khan and ElSohly did. It was dependent on -- there's a litany of what's here and why the rendering was made by the agency that it doesn't fit into a dietary ingredient.

So, you know, it's not appropriate for the space. It's not a dietary ingredient. It's something that was a drug that all of a sudden, almost 50 years after the fact of it being approved as a drug, somebody finds it in nature? That doesn't happen in the natural products world. Could it happen? Possibly, but it doesn't happen.

So again, I think -- I don't see -- I guess we just have a difference of how we see it, Mr. Wenik.

Q Fair enough.

Did ElSohly ever communicate to you that Shanghai Institute of Materia Medica had detected DMAA in any amount in a geranium sample?

A I don't recall.

Q How about Dr. Khan?

A I don't recall.

MR. WENIK: I have nothing further.

THE WITNESS: Okay.

MR. SCOTT: I have just a couple.

EXAMINATION BY COUNSEL FOR UNITED STATES

BY MR. SCOTT:

Q In a couple of instances, Mr. Wenik asked you about the burden that would be on FDA to ban a dietary ingredient.

Do you recall that?

A Yes.

Q Did FDA conclude that DMAA was a dietary ingredient?

A No. It concluded it was not. It concluded it was an unapproved food additive, and therefore it couldn't be banned as a dietary ingredient.

Q As an unapproved food additive, would it

be subject to the provisions of regulations that require NDI?

A It could. More than likely it would be required to show -- it would either have to have a full food additive petition or a full GRAS notification, more than likely.

Q And if it had neither of those, would it be considered that products including it that are being sold as foods to be adulterated?

MR. WENIK: Objection to form.

THE WITNESS: Yes.

BY MR. SCOTT:

Q And to your knowledge, were either of the paths to NDI followed in relation to DMAA?

A No.

MR. SCOTT: No further questions.

MR. WENIK: I have no redirect. I thank you for your courtesy.

MR. SCOTT: He will read and sign.

(Signature having not been waived, the deposition of DANIEL FABRICANT, Ph.D. was concluded at 2:41 p.m.)

ACKNOWLEDGEMENT OF WITNESS

I, Daniel Fabricant, Ph.D., do hereby acknowledge that I have read and examined the foregoing testimony, and the same is a true, correct and complete transcription of the testimony given by me, and any corrections appear on the attached Errata sheet signed by me.

_____ _____

(DATE) (SIGNATURE)

Daniel Fabricant, Ph.D.

E R R A T A S H E E T

DATE:

WITNESS:

CASE:

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(DATE) (SIGNATURE)

Daniel Fabricant, Ph.D.

CERTIFICATE OF SHORTHAND REPORTER -- NOTARY PUBLIC

I, Laurie Donovan, Registered Professional Reporter, Certified Realtime Reporter, the officer before whom the foregoing deposition was taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that said testimony was taken by me stenographically and thereafter reduced to typewriting under my supervision; and that I am neither counsel for, related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 28th day of November, 2016.

My commission expires: March 14th, 2021

_____

LAURIE DONOVAN
NOTARY PUBLIC IN AND FOR
THE DISTRICT OF COLUMBIA